The Honorable Barbara J. Rothstein

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

THE BILL & MELINDA GATES FOUNDATION, a charitable trust organized under the laws of the State of Washington, Plaintiff, v. PNUVAX INCORPORATED, a Canadian corporation, Defendant.	No.: 2:19-cv-00308-BJR **AMENDED COMPLAINT FOR BREACH OF CONTRACT AND FOR DECLARATORY RELIEF**

The Bill & Melinda Gates Foundation, by and through its counsel K&L Gates LLP, brings this action against defendant PnuVax Incorporated ("PnuVax Inc.") for recovery of damages owed for breach of contract and for declaratory relief. In support thereof, plaintiff alleges the following:

I. INTRODUCTION

1. The Bill & Melinda Gates Foundation (the "Foundation") is a private philanthropic foundation and the largest charitable foundation in the world. To bring about change that will help people live healthier and more productive lives, the Foundation identifies program strategies to address global inequities in development, health, and

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education. The Foundation carries out these strategies in collaboration with other organizations (collectively, "Grantees") by providing grants to Grantees. In 2017, the Foundation invested $4.7 billion in its charitable programs.

2. One such program strategy aims to reduce the top killer of children under 5 years of age in developing countries: pneumonia. Childhood deaths from pneumonia are preventable using existing vaccines and diagnostic tools, but those vaccines and tools are often too expensive or not accessible to children in developing countries. The Foundation's Pneumonia Strategy Team works to improve the development and delivery of affordable and accessible pneumonia vaccines and treatments for these children. To that end, the Pneumonia Strategy Team makes a portfolio of grants to reduce the burden of pneumococcal infections by expanding coverage of existing vaccines, developing lower-cost vaccines that provide equal or greater protection, and generating evidence for sustainable, more affordable pneumococcal immunization programs.

3. One former Grantee of the Foundation's Pneumonia Strategy Team is PnuVax Inc. Beginning in 2014, the Foundation and PnuVax Inc. entered into three successive grant agreements for the development of a 13-valent pneumococcal conjugate vaccine, which PnuVax Inc. promised could be distributed to developing countries at a low cost (the "Vaccine"). The goal of Foundation grants related to the Vaccine was to provide low-cost access to reduce the occurrence of pneumonia and associated childhood deaths.

4. This lawsuit arises under the third grant agreement between PnuVax Inc. and the Foundation, which was signed in August 2017 and provided for PnuVax Inc. to receive up to US$29,423,549.00 in grant funds to develop the Vaccine. The grant agreement also

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authorized the Foundation to withhold grant funds and/or terminate the agreement if PnuVax Inc. failed to comply with its terms and conditions. After the Foundation paid PnuVax Inc. US$3 million in August 2017 under the grant agreement, PnuVax Inc. materially breached the grant agreement in multiple respects.

5. When it suspected a breach, the Foundation hired an independent third-party auditor, KPMG, to review the books and records of PnuVax Inc. and its subcontractor. KPMG's audit findings, which are summarized in Exhibit 1, confirmed that PnuVax Inc. had breached the grant agreement. They also described numerous categories of improper conduct by PnuVax Inc., including the following:

- PnuVax Inc. misused grant funds;
- PnuVax Inc. made unauthorized pre-grant expenditures, including expenditures for materials and equipment that were manufactured and/or invoiced prior to the grant start date;
- The subcontractor used by PnuVax Inc., which is controlled by the same individuals as PnuVax Inc., charged a 40% mark-up on personnel costs and a 15% mark-up on materials—a fact not disclosed to the Foundation;
- Almost immediately after entering into the grant agreement and receiving US$3 million in grant funds, PnuVax Inc. diverted these funds to a trust account maintained by its attorney and used the funds to pay significant amounts of back rent owed to its landlord;
- PnuVax Inc. failed to keep adequate financial records and failed to segregate grant funds; and

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- PnuVax Inc. failed to properly apply earned interest to the charitable project.

6. As a result of PnuVax Inc.'s contract breaches and improper conduct, the Foundation terminated the grant agreement and asked PnuVax Inc. to produce a final report to the Foundation. In response, PnuVax Inc. submitted an incomplete report and demanded that the Foundation pay it over US$11 million in additional funds under the grant agreement.

7. The Foundation brings this suit to recover its damages for PnuVax Inc.'s breaches of the grant agreement. The Foundation also seeks a declaration that it has no obligation to pay any additional sums to PnuVax Inc. and that to pay PnuVax Inc. anything further in these circumstances would violate the requirements of the Internal Revenue Code.

II. PARTIES

8. The Foundation is a charitable trust organized under the laws of the State of Washington and a private foundation under 26 U.S.C. § 501(c)(3). The Foundation's principal place of business, and the headquarters for its operations, is in Seattle, Washington. The Foundation's officers direct, control, and coordinate the Foundation's activities from its Seattle headquarters.

9. PnuVax Inc. is a for-profit Canadian corporation with its principal place of business located at 134 Albert Street, Kingston, Ontario K7L3V2. Its CEO is Donald Gerson.

III. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action under 28 U.S.C. § 1332 because PnuVax Inc. is a Canadian entity; the Foundation is a tax-exempt private foundation with its principal place of business in Seattle, Washington; and the amount in controversy exceeds $75,000, exclusive of interest and costs.

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11. Venue is proper under 28 U.S.C. § 1391(b) because PnuVax Inc. is subject to this Court's personal jurisdiction with respect to this civil action; because a substantial part of the events or omissions giving rise to the claims occurred in this District; and because a substantial part of the property that is the subject of this action is located in this District.

12. This Court may declare the legal rights and obligations of the parties in this action pursuant to 28 U.S.C. §§ 2201 and 2202 because the action presents an actual controversy within the Court's jurisdiction.

IV. GENERAL ALLEGATIONS

A. PnuVax Inc. Agrees to Develop a Low-Cost Vaccine for Pneumonia

13. According to its website, PnuVax Inc. is "dedicated to the production of high quality biopharmaceuticals for the promotion of public health worldwide." Over the last five years, the Foundation has entered into three separate grant agreements with PnuVax Inc. to fund ultimately the development of a low-cost 13-valent pneumococcal conjugate vaccine to be used in developing countries. The Foundation and PnuVax Inc. had numerous conversations in which they developed the Project proposal documents, discussed the development of the Vaccine, and monitored PnuVax Inc.'s progress toward achieving the milestones described in the grant agreements. The grant agreements budgeted for PnuVax Inc.'s CEO to travel to Seattle and meet with Foundation leadership. In addition, PnuVax Inc.'s CEO participated in the Foundation-sponsored Product Development Forum held in Seattle in April 2015.

14. The Foundation's relationship with PnuVax Inc. began in 2014. PnuVax Inc. and the Foundation entered into their first grant agreement dated February 28, 2014, for the

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purpose of implementing the conjugation technology underlying the Vaccine and to bring it through successful animal testing. At that time, the science underlying the Vaccine was in its early stages. The amount of the first grant was up to US$5,999,614. The Foundation and PnuVax Inc. entered into a second grant agreement on August 5, 2015, for an amount of up to US$3,298,464 for the purpose of further evaluating the efficiency of the conjugation technology for making the Vaccine and generating data that would demonstrate the Vaccine's non-inferiority compared to an existing 13-valent pneumococcal conjugate vaccine. Both grants were for the charitable purpose of supporting PnuVax Inc.'s preclinical development of the Vaccine in support of the Foundation's strategy to reduce the health burden of pneumonia for children under 5 years of age in developing countries.

B. The Parties Enter into the Grant Agreement that is the Subject of this Complaint

15. On August 17, 2017, the Foundation and PnuVax Inc. entered into their third grant agreement (the "Grant Agreement"). The Grant Agreement describes the terms and conditions upon which the Foundation would provide "[u]p to $29,423,549.00" in grant funding to PnuVax Inc. to advance the clinical development and bio-manufacturing scale-up of the Vaccine. As this was PnuVax Inc.'s third "up to" grant from the Foundation with milestones, PnuVax Inc. was well aware of the conditions for payment under the Grant Agreement.

16. PnuVax Inc. was a small company that was newly formed at the time that the parties entered into the first grant agreement. PnuVax Inc.'s reporting to the Foundation under the terms of the first two grant agreements was minimal. This led the Foundation to include additional milestones in the Grant Agreement, which were appropriate for the stage

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of development of the Vaccine. Given the Foundation's past experience with PnuVax Inc., the Foundation made sure that the provision of grant funds under the Grant Agreement was conditioned on compliance by PnuVax Inc. with detailed requirements and its achievement of project milestones.

17. The Grant Agreement consists of multiple documents, including a Grant Amount and Reporting & Payment Schedule (Attachment A); Terms and Conditions (Attachment B); and Global Access Commitment Agreement (Attachment C). The Grant Agreement also incorporates the Proposal Narrative submitted on July 24, 2017, and the Budget submitted on July 24, 2017. A true and correct copy of the Grant Agreement is attached hereto as Exhibit 2.

18. The Grant Agreement in Attachment B states that "[t]he Foundation is awarding You [i.e., PnuVax Inc.] this grant to carry out the project described in the Proposal Narrative and Results Framework and Tracker (collectively, "*Project*") in order to further the Charitable Purpose." The subsequent paragraph of the Grant Agreement, entitled "Use of Funds," states as follows:

> You may not use funds provided under this Agreement ("Grant Funds") for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date.

19. The Foundation's commitment to provide grant funding to PnuVax Inc. under the Grant Agreement was continually subject to the terms and conditions set forth therein, including the requirement that PnuVax Inc. remain in compliance with the Grant Agreement and the requirement that PnuVax Inc. meet certain milestones in connection with its efforts to develop the Vaccine. The Grant Agreement states as follows:

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> **REPORTING & PAYMENT SCHEDULE**
> Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

20. The Grant Agreement, by its terms, is also subject to the "expenditure responsibility" requirements under the United States Internal Revenue Code (the "IRC"). Under IRC Section 4945(h), expenditure responsibility means that a private foundation is responsible to exert all reasonable efforts and to establish adequate procedures (1) to see that the grant is spent solely for the purpose for which made; (2) to obtain full and complete reports from the grantee on how the funds are spent; and (3) to make full and detailed reports with respect to such expenditures to the IRS.

21. Consistent with these expenditure responsibility requirements and the requirements set forth in 26 C.F.R. § 53.4945-5, the Grant Agreement obligates PnuVax Inc. to use Grant Funds solely for purposes of the Foundation's Project and in compliance with the Grant Agreement; to submit progress reports according to the Reporting & Payment Schedule; to track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Grant Funds; and to maintain adequate accounting records.

22. The Reporting & Payment Schedule of the Grant Agreement describes the potential Grant Funds to which PnuVax Inc. would have access in order to complete the Foundation's Project, if PnuVax Inc. remained in compliance with the terms and conditions of the Grant Agreement. That schedule conditions the payment, in increments, of "up to"

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US$29,423,549.00 in Grant Funds upon the achievement by PnuVax Inc. of identified targets, milestones, and reporting deliverables.

23. The terms and conditions of the Grant Agreement include, but are not limited to, the following:

- PnuVax Inc. may not use grant funds for any purpose other than the Project.
- PnuVax Inc. may not use any grant funds to pay for expenses it incurred prior to August 17, 2017.
- PnuVax Inc. must invest grant funds in highly liquid investments and report the amount of any conversion gains (or losses) and the amount of any interest or other income generated by the grant funds. Any income must be used for the Project.
- PnuVax Inc. must maintain the grant funds in a physically separate bank account or a separate bookkeeping account maintained as part of its financial records and dedicated to the Project.
- PnuVax Inc. must maintain adequate accounting records and copies of any reports submitted to the Foundation relating to the Project.
- PnuVax Inc. must ensure that its subcontractors comply with the terms of the Grant Agreement.

24. The Grant Agreement authorized PnuVax Inc., on certain terms and conditions, to select subgrantees and subcontractors to assist with the Project. The Grant Agreement made PnuVax Inc. responsible for ensuring that its subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project complied with the terms of the Grant Agreement.

25. PnuVax Inc. designated and used PnuVax SL Biopharmaceuticals, Inc. ("PnuVax SL") to act as its principal subcontractor with respect to the Project. The relationship between PnuVax Inc. and PnuVax SL is not an arm's-length relationship. PnuVax SL has no operational or business objective other than to carry out the objectives of

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PnuVax Inc. The individuals controlling PnuVax SL are the same individuals who control PnuVax Inc.

26. The Grant Agreement had an end date of December 31, 2019, unless terminated by the Foundation prior to the end date. The Grant Agreement authorized the Foundation to terminate the Grant Agreement if PnuVax Inc. failed to comply with its terms. The termination provision in the Grant Agreement provides as follows:

> **TERMINATION**
> The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your Progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

27. Upon termination of the Grant Agreement, the next paragraph provides, "[a]ny Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation."

C. Suspicion and Confirmation of Material Breach

28. After the parties executed the Grant Agreement, the Foundation made the first payment of Grant Funds, in the amount of US$3,000,000, to PnuVax Inc. PnuVax Inc. failed to achieve the first milestone under the Grant Agreement, Milestone 1, which required that PnuVax Inc. submit 2016 audited financial statements by September 30, 2017. Then, in November 2017, the Foundation learned from a newspaper article that PnuVax Inc. had owed the Canadian government approximately $1 million (CAD) in back rent and that PnuVax Inc. had allegedly paid its back rent obligation by using Grant Funds provided by the Foundation.

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The Grant Agreement forbade using Grant Funds to pay rental expenses that accrued prior to the start date of the Grant Agreement or outside of the agreed Project activities.

29. In accordance with the Reporting & Payment Schedule of the Grant Agreement, PnuVax Inc. provided a Progress Report to the Foundation in January 2018 detailing the Project's progress and reporting actual expenditures during the initial Investment Period (August 17 through December 31, 2017). In that Progress Report, PnuVax Inc. stated that, of the initial payment of US$3,000,000, actual expenditures during the initial Investment Period totaled US$2,142,777, leaving US$857,223 in unexpended Grant Funds.

30. The Foundation engaged KPMG to conduct an audit of PnuVax Inc.'s expenditure of Grant Funds during the initial Investment Period (i.e., August 17 through December 31, 2017). KPMG conducted its audit over the course of approximately six months, beginning in February 2018. PnuVax Inc. and PnuVax SL failed to cooperate in the audit and were contentious throughout. The results of the audit supported the conclusion that PnuVax Inc. was not in compliance with the Grant Agreement and had violated its terms and conditions in many respects.

31. In addition to PnuVax Inc.'s material breaches, PnuVax Inc.'s contentious behavior, continual delays, secrecy, evasiveness, and lack of transparency were factors that the Foundation reasonably believed threatened the Project's success.

D. PnuVax Inc.'s Breaches of Grant Agreement

32. The KPMG audit revealed that PnuVax Inc. had breached the Grant Agreement in numerous respects. PnuVax Inc. failed to comply with restrictions on the use of Grant Funds; failed to maintain adequate records; failed to properly segregate Grant Funds;

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and used Grant Funds improperly, including by paying for expenses incurred prior to the start date of the Grant Agreement. PnuVax Inc. also failed to meet four project milestones, did not use income earned on the Grant Funds for the Project, and failed to properly evidence work done under the grant as required by the Grant Agreement and its expenditure responsibility provisions.

33. Among the actions and inactions by PnuVax Inc. that were improper, that violated the terms of the Grant Agreement, or both, are the following:

(a) PnuVax Inc. transferred approximately $2 million (CAD) in grant funds received from the Foundation to its legal counsel in November 2017. Such monies were placed in an interest-bearing trust account. PnuVax Inc. used a portion of these funds to pay its back rent obligation to the National Research Council and to pay outstanding property tax bills. These obligations had accrued prior to the start date of the Grant Agreement and were not related to the agreed charitable Project activities.

(b) PnuVax Inc. failed to properly segregate the Grant Funds. For instance, shareholder loan funds were deposited in the same bank accounts that held the Grant Funds. PnuVax Inc. also caused inflows and outflows of Grant Funds across several bank accounts of PnuVax Inc. and PnuVax SL, which caused the Grant Funds to be commingled with non-Grant Funds. In addition, PnuVax Inc. failed to properly maintain a separate bookkeeping account, which could have been utilized in lieu of the dedicated bank account.

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(c) PnuVax Inc. used Grant Funds to pay additional expenses that were incurred prior to the start date of the Grant Agreement, including equipment charges, materials costs, and direct facility costs.

(d) PnuVax Inc.'s records related to the reporting of grant-related expenditures contain errors or inconsistencies, which reflect that PnuVax Inc.'s financial record-keeping was inadequate.

(e) PnuVax Inc. did not have a process or protocol for monitoring, on an ongoing basis, actual expenditures compared to budgeted expenditures. As a result, its financial accounting records were inadequate.

(f) PnuVax Inc. failed to achieve Milestone 1 by not submitting audited financial statements for fiscal year 2016, including an auditor's opinion, by September 30, 2017.

(g) PnuVax Inc. failed to achieve Milestone 2, preparing clinical trial doses of the Vaccine by February 28, 2018, due in part to failure of achieving Milestone 1.

(h) PnuVax Inc. failed to achieve Milestone 3 by not submitting audited financial statements for fiscal year 2017, including an auditor's opinion, by May 1, 2018.

(i) PnuVax Inc. failed to achieve Milestone 4 by not hiring a Finance Director by May 1, 2018.

34. On September 12, 2018, the Foundation sent PnuVax Inc. a termination notice via email and a hard copy by FedEx, which stated that the Foundation was terminating the

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Grant Agreement for material breach and failure to comply with its terms. A true copy of this email (without its attachments) is attached as Exhibit 3. The Foundation instructed PnuVax Inc. to provide a final report on the Project; to return, within 30 days, all Grant Funds that had not been used for, or committed to, the Project; and to return, within 30 days, an amount equal to the interest earned on the Grant Funds held in the trust account of PnuVax Inc.'s legal counsel.

35. PnuVax Inc. submitted an incomplete Final Narrative to the Foundation on or about October 11, 2018. The incomplete Final Narrative failed to provide any explanation of how PnuVax Inc. had spent the US$857,223 in Grant Funds that remained at the end of the initial Investment Period. PnuVax Inc. stated in its incomplete Final Narrative that there were no Grant Funds or interest earned thereon to return to the Foundation. PnuVax Inc. claimed that US$3,872,861 in total work had been performed under the Grant Agreement, leaving a balance of US$872,861 owed to PnuVax Inc. on top of the Foundation's initial US$3 million payment. But PnuVax Inc. provided no evidence or explanation of the work that it had allegedly performed in furtherance of the Project activities. PnuVax Inc. also claimed to be owed a total of US$11,629,365.00 under the Grant Agreement, a claim repeated in subsequent correspondence from PnuVax Inc.'s lawyer.

V. FIRST CAUSE OF ACTION—Breach of Contract

36. The Foundation incorporates and re-alleges the foregoing paragraphs as if fully set forth herein.

37. The Grant Agreement attached hereto as Exhibit 2 and all documents incorporated therein, including the Proposal Narrative submitted July 24, 2017, and Budget

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submitted July 24, 2017, constitute a single integrated and enforceable contract.

38. The Foundation performed all conditions, covenants, and promises it was required to perform under the terms of the Grant Agreement.

39. PnuVax Inc. is a signatory and party to the Grant Agreement.

40. Through the acts described above, PnuVax Inc. materially breached the Grant Agreement, including the Grant Agreement's requirement that PnuVax Inc. not use Grant Funds for any purpose other than the Project; the requirement that PnuVax Inc. segregate Grant Funds; the requirement that PnuVax Inc. maintain adequate accounting records; the requirement that PnuVax Inc. timely fulfill Project milestones; and the requirement that PnuVax Inc. comply with the reporting requirements in accordance with the Grant Agreement;

41. The Foundation has been damaged by PnuVax Inc.'s breaches of the Grant Agreement and is entitled to judgment for the amount of Grant Funds, plus interest thereon, that PnuVax Inc. failed to use for expenditures related to the Project and that PnuVax Inc. spent in ways not authorized under the Grant Agreement.

VI. SECOND CAUSE OF ACTION—Declaratory Relief

42. The Foundation incorporates and re-alleges the foregoing paragraphs as if fully set forth herein.

43. As evidenced by PnuVax Inc.'s demands for payment of over US$11 million in additional funds under the Grant Agreement, there exists an actual and justiciable controversy within the jurisdiction of this Court as to which the Court may declare the rights, status, or other legal relations of the parties. Pursuant to 28 U.S.C. § 2201(a), this Court may

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declare the rights and legal relationship of PnuVax Inc. and the Foundation with respect to their respective obligations under the Grant Agreement. Resolving the controversies related to the Grant Agreement is necessary to the continued proper operation and realization of the purposes of the Foundation and its enjoyment of the rights and privileges of ownership of its property and assets.

44. The Foundation is entitled to entry of a judgment declaring as follows:

(a) PnuVax Inc. failed to comply with the terms and conditions of the Grant Agreement;

(b) The Foundation was authorized to suspend and withhold Grant Funds on account of PnuVax Inc.'s failure to comply with the terms and conditions of the Grant Agreement;

(c) The Foundation lawfully terminated the Grant Agreement; and

(d) The Foundation has no obligation to pay any further sums to PnuVax Inc. under the Grant Agreement.

VII. RELIEF REQUESTED

The Foundation respectfully requests that this Court enter judgment in its favor and against PnuVax Inc. as follows:

1. A money judgment against PnuVax Inc. on the Foundation's breach of contract claim in an amount to be proven at trial;

2. Prejudgment interest;

3. An award of the Foundation's attorneys' fees and costs incurred in this action;

4. A judgment declaring the following:

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(a) PnuVax Inc. failed to comply with the terms and conditions of the Grant Agreement;

(b) The Foundation was authorized to suspend and withhold Grant Funds on account of PnuVax Inc.'s failure to comply with the terms and conditions of the Grant Agreement;

(c) The Foundation lawfully terminated the Grant Agreement on or about September 11, 2018; and

(d) The Foundation has no obligation to pay any additional sums to PnuVax Inc.; and

5. Such other and further relief as this Court deems just and proper.

DATED this 12th day of March 2019.

K&L GATES LLP

By */s/ Robert Mitchell*
Robert B. Mitchell, WSBA #10874
By */s/ Kari L. Vander Stoep*
Kari Vander Stoep, WSBA #35923
By */s/ Brian T. Peterson*
Brian T. Peterson, WSBA #42088
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Attorneys for Bill & Melinda Gates Foundation

EXHIBIT 1

KPMG

Bill and Melinda Gates Foundation

Grant Expenditure Evaluation Report

Grantee: PnuVax, Inc.

Grant Number: OPP1172539

On-site Evaluation Completed: August 14, 2018

DRAFT-FOR DISCUSSION PURPOSES ONLY

Executive summary

The findings and additional observations contained in this report are based primarily upon the information and data supplied to KPMG by PnuVax Inc., and PnuVax SL management. It is important to note that we received multiple iterations of the documentation requested in the course of our analysis. In a number of instances, this information was either incomplete or contradictory in its content. For consistency purposes KPMG has used the last iteration of data provided on May 18, 2018 as the baseline for this evaluation. However, we make no representations as to the completeness or accuracy of this information nor are we responsible for updating this report for changes or modifications in the source documents provided.

Executive Summary	Section	Conclusion	Observation	Page
The following summarizes the observations made during the course of this evaluation.				
Grant expenditure review • Inconsistent use of funds, including misuse of funds, discrepancies in actuals, expenses incurred prior to grant start date.	**Use and reporting of funds**	**Requires urgent action**	**1**	**6**
Limited cash flow analysis • Potential diversion of funds	**Use and reporting of funds**	**Requires urgent action**	**2**	**10**
Segregation of grant funds • No segregation of grant funds	**Compliance with grant agreement**	**Requires urgent action**	**3**	**12**
Tracking of interest income • Failure to remit interest on invested grant funds	**Compliance with grant agreement**	**Requires urgent action**	**4**	**13**
Maintenance of appropriate records • Failure to keep appropriate records	**Compliance with grant agreement**	**Requires urgent action**	**5**	**13**
Budget monitoring practices • Insufficient budget to actual expenditure monitoring	**Compliance with grant agreement**	**Requires urgent action**	**6**	**14**
Subgrantee management • Incorrect treatment of project partners (subcontractors)	**Compliance with grant agreement**	**Requires urgent action**	**7**	**15**

Executive Summary	Section	Conclusion	Observation	Page
Financial sustainability (Non-BMGF inflows) • Transparency of financial information to Foundation	**Operational issues**	**Requires urgent action**	8	16
Ownership of capital assets • Provision of capital asset documentation	**Operational issues**	**Requires urgent action**	9	17
Project milestone completion • Delayed completion of project milestones	**Operational issues**	**Requires urgent action**	10	17
Staffing capacity • Vacancy in key staff position	**Operational issues**	**Requires strengthening and follow-up**	11	18
Overhead charges • Incorrect calculation of overhead	**Operational issues**	**Requires strengthening and follow-up**	12	19
Policies and procedures • Undocumented policies and procedures	**Operational issues**	**Requires strengthening and follow-up**	13	19
Board involvement • Provision of board documentation	**Operational issues**	**Requires strengthening and follow-up**	14	20
Tax reporting • Confirmation of tax compliance requirements	**Operational issues**	**Generally adequate and functioning**	15	20

EXHIBIT 2

BILL & MELINDA GATES foundation

GRANT AGREEMENT
Investment ID OPP1172539

AGREEMENT SUMMARY & SIGNATURE PAGE

GRANTEE INFORMATION	
Name:	PnuVax Incorporated
Tax Status:	Not exempt from federal income tax under U.S. IRC § 501(c)(3) You confirm that the above information is correct and agree to notify the Foundation immediately of any change.
Expenditure Responsibility:	This Agreement is subject to "expenditure responsibility" requirements under the U.S. Internal Revenue Code.
Mailing Address:	134 Albert Street Kingston, ON, K7L3V2 Canada
Primary Contact:	Donald Gerson, CEO, [redacted]

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, WA 98102, U.S.A.
Primary Contact:	Janet White, Portfolio and Platform Lead, Janet.White@gatesfoundation.org

AGREEMENT INFORMATION	
Title:	PnuVax PCV13 - development of vaccine through POC in infants
"Charitable Purpose":	To develop a 13-valent pneumococcal conjugate vaccine that is available to GAVI countries at an affordable price
"Start Date":	Date of last signature.
"End Date":	December 31, 2019
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Proposal Narrative (date submitted July 24, 2017) • Budget (date submitted July 24, 2017) • Global Access Commitment Agreement (Attachment C)

THIS AGREEMENT is between PnuVax Incorporated ("*You*" or "*Grantee*") and the Bill & Melinda Gates Foundation ("*Foundation*"), and is effective as of the date of last signature. Each party to this Agreement may be referred to individually as a "*Party*" and together as the "*Parties.*" As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

DocuSigned by:
Trevor Mundel
DD5444F322CE4A9...

By: Trevor Mundel
Title: President, Global Health

August 17, 2017
Date

PNUVAX INCORPORATED

DocuSigned by:
F6BEF7E3F9B6475...

By: Donald Gerson
Title: CEO

August 17, 2017
Date

GRANT AGREEMENT
Investment ID OPP1172539

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT
The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE
Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING
You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

ACCOUNTING FOR PERSONNEL TIME
You will track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Grant Funds. Such individuals will keep records (e.g., timesheets) of actual time worked on the Project in increments of sixty minutes or less and brief descriptions of tasks performed. You will report actual time worked consistent with those records in Your progress and final budget reports. You will submit copies of such records to the Foundation upon request.

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		Within 15 days after receipt of countersigned Agreement	$3,000,000.00
	Milestone 1: Satisfactory submission of formally audited FY2016 financial statements for PnuVax Inc and PnuVax SL including auditor's opinion	September 30, 2017	October 2017	Up to $6,090,344.00
Start Date - December 31, 2017	Satisfactory Progress Report	January 31, 2018	February 2018	Up to $3,846,340.00
	Go / No-Go / Milestone 2: * Clinical Trial Doses Prepared - Satisfactory completion of FIH Milestone per the IPDP * Submission of updated IPDP	February 28, 2018	March 2018	Up to $2,700,000.00
	Milestone 3: Satisfactory submission of (1) formally audited FY2017 financial statements for PnuVax Inc and PnuVax SL including auditor's opinion and (2) cash on hand as of May 1, 2018 **Milestone 4**: Hiring of Finance Director with capacity to lead the finance and accounting functions and prepare financial and management information to PnuVax leadership and external auditors	May 1, 2018	June 2018	Up to $1,692,681.00
	Go / No Go Milestone: • Phase 1 Trial Executed – End of Phase 1 Stage Gate per the IPDP • Submission of updated IPDP	August 31, 2018	September 2018	Up to $1,846,340.00
January 1, 2018- December 31, 2018	Satisfactory Progress Report	January 31, 2019	March 2019	Up to $5,623,922.00
	Milestone 5: Satisfactory submission of (1) formally audited FY2018 financial statements for PnuVax Inc and PnuVax SL including auditor's opinion and (2) cash on hand as of May 1, 2019	May 1, 2019	July 2019	Up to $4,623,922.00
Start Date – End Date	Final Report	Within 90 days of End Date		
			Total Grant Amount	Up to $29,423,549.00

GRANT AGREEMENT
Investment ID OPP1172539

ATTACHMENT B
TERMS & CONDITIONS

This Agreement is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE

The Foundation is awarding You this grant to carry out the project described in the Proposal Narrative and Results Framework and Tracker (collectively, "*Project*") in order to further the Charitable Purpose.

MANAGEMENT OF FUNDS

USE OF FUNDS

You may not use funds provided under this Agreement ("*Grant Funds*") for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date.

INVESTMENT OF FUNDS

You must invest Grant Funds in highly liquid investments with the primary objective of preservation of principal (e.g., interest-bearing bank accounts or a registered money market mutual fund) so that the Grant Funds are available for the Project. Together with any progress or final reports required under this Agreement, You must report the amount of any currency conversion gains (or losses) and the amount of any interest, or other income generated by the Grant Funds (collectively, *"Income"*). Any Income must be used for the Project.

SEGREGATION OF FUNDS

You must maintain Grant Funds in a physically separate bank account or a separate bookkeeping account maintained as part of Your financial records and dedicated to the Project.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

In furtherance of Your Global Access Commitments, You are entering into the Global Access Commitment Agreement attached as Appendix C.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. "*Publication*" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best

furthers Global Access. If You seek Publication in a peer-reviewed journal, such Publication shall be under "open access" terms and conditions consistent with the Foundation's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (*e.g.*, © 20<> <Name>).

INTELLECTUAL PROPERTY REPORTING
During the term of this Agreement and for 5 years after, You will submit upon request annual intellectual property reports related to the Funded Developments, Background Technology, and any related agreements using the Foundation's templates or forms, which the Foundation may modify from time to time.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS
Provided that You do not make subgrants to individuals under this Agreement, You have the exclusive right to select subgrantees and subcontractors to assist with the Project. If You use Grant Funds to make a subgrant to an organization that is not a U.S. public charity or government agency/instrumentality, You must comply with the expenditure responsibility procedures available at: www.gatesfoundation.org/Documents/Expenditure%20Responsibility%20Procedures%20for%20Subgrants.docx.

RESPONSIBILITY FOR OTHERS
You are responsible for (a) all acts and omissions of any of Your trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project, and (b) ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM
You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, (North) Sudan, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY
You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

POLITICAL ACTIVITY AND ADVOCACY
You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You may not use Grant Funds to support lobbying activity or to otherwise support attempts to influence local, state, federal, or foreign legislation. Your strategies and activities, and any materials produced with Grant Funds, must comply with applicable local, state, federal, or foreign lobbying law. You agree to comply with lobbying, gift, and ethics rules applicable to the Project.

PUBLICITY

PUBLICITY BY THE FOUNDATION
The Foundation may include information about the award of this grant, including Your name, in its periodic

public reports and may make such information available on its website and as part of press releases, public reports, speeches, newsletters, tax returns, and other public disclosures.

PUBLICITY BY YOU
You must obtain the Foundation's prior written approval before: (a) issuing a press release or other public announcement regarding this grant; and (b) any other public use of the Foundation's name or logo. Please email Your request to: grantee.comms@gatesfoundation.org two weeks in advance to provide the Foundation an opportunity to review and comment. Detailed guidelines are available at: www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PUBLICITY BY OTHERS
You and Your subgrantees, subcontractors, contingent workers, agents, or affiliates may not state or otherwise imply to third parties that the Foundation directly funds or otherwise endorses their activities.

OTHER

COMPLIANCE WITH LAWS
In carrying out the Project, You will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.

COMPLIANCE WITH REQUIREMENTS
You will conduct, control, manage, and monitor the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards ("*Requirements*"). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of Your annual progress report to the Foundation, you must report whether the Project activities were conducted in compliance with all Requirements.

If the Project involves:
a. any protected information (including personally identifiable, protected health, or third-party confidential), You will not disclose this information to the Foundation without obtaining the Foundation's prior written approval and all necessary consents to disclose such information;
b. children or vulnerable subjects, You will obtain any necessary consents and approvals unique to these subjects; and/or
c. any trial involving human subjects, You will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the Foundation in reviewing documents and providing input or funding does not modify Your responsibility for determining and complying with all Requirements for the Project.

RELIANCE
You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

INDEMNIFICATION
If the Project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("*Indemnified Activities*"), You will indemnify, defend, and hold harmless the Foundation and its trustees, employees, and agents ("*Indemnified Parties*") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "*Claims*") arising out of or relating to the acts or omissions, actual or alleged, of You or Your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive

the Foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of Your governmental and sovereign immunities, if any.

INSURANCE
You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted industry standards and as required by law. You will ensure Your subgrantees and subcontractors maintain insurance coverage consistent with this section.

TERM AND TERMINATION

TERM
This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement.

TERMINATION
The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS
Any Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation.

RECORD KEEPING
You will maintain adequate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Grant Funds are fully spent and will make such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used.

SURVIVAL
A Party's obligations under this Agreement will be continuous and survive expiration or termination of this Agreement as expressly provided in this Agreement or otherwise required by law or intended by their nature.

GENERAL

ENTIRE AGREEMENT AND AMENDMENTS
This Agreement contains the entire agreement of the Parties and supersedes all prior and contemporaneous agreements concerning its subject matter. Except as specifically permitted in this Agreement, no modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

NOTICES AND APPROVALS
Written notices, requests, and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the Agreement Summary & Signature Page, or as otherwise directed by the other Party.

SEVERABILITY
Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

ASSIGNMENT
You may not assign, or transfer by operation of law or court order, any of Your rights or obligations under this Agreement without the Foundation's prior written approval. This Agreement will bind and benefit any permitted successors and assigns.

COUNTERPARTS AND ELECTRONIC SIGNATURES
Except as may be prohibited by applicable law or regulation, this Agreement and any amendment may be signed in counterparts, by facsimile, PDF, or other electronic means, each of which will be deemed an original and all of which when taken together will constitute one agreement. Facsimile and electronic signatures will be binding for all purposes.

GLOBAL ACCESS COMMITMENT AGREEMENT
Investment ID OPP1172539

ATTACHMENT C

This Global Access Commitment Agreement ("**Agreement**") is made as of the last date of signature below ("**Effective Date**") between the Bill & Melinda Gates Foundation, a Washington Charitable Trust (the "**Foundation**"), and PnuVax Incorporated, a Canadian corporation ("**PnuVax**" or the "**Company**"). Each of these entities may be referred to as a "**Party**" and collectively as the "**Parties**."

Background

- The Foundation, in furtherance of its charitable purposes, wishes to ensure that a PCV-13 pneumococcal conjugate vaccine is available and affordable to those most in need in developing world countries.

- The Company possesses expertise in the manufacturing, distribution and sale of vaccines and desires to develop and manufacture a PCV-13 pneumococcal conjugate vaccine ("**Product**") and to make this Product available and affordable to those most in need in developing world countries.

- The Company has Background IP that enables PnuVax to manufacture PnuVax PCV-13.

- The Company wishes to commit to manufacture and supply certain volumes of the Product to those countries listed or described in Appendix A ("**Designated Countries**") at or below an agreed-on price or as otherwise specified in this Agreement during the Term (defined below) and subject to the provisions outlined herein in exchange for funding from the Foundation under the grant made under OPP1172539 and the related Grant Agreement between the Parties dated as of the Effective Date ("**Grant Agreement**").

Accordingly, the Parties agree as follows:

Agreement

1. **Definitions**

"Advance Market Commitment for Pneumococcal Vaccines" or "**AMC**" means an initiative to encourage private sector investment to accelerate the availability of targeted pneumococcal vaccines for developing countries in relation to which Gavi is a stakeholder, comprised in part of a legally binding commitment to support the market for these vaccines with payments to manufacturers in consideration of these manufacturers' commitment to supply an annual share of doses of these vaccines at a pre-determined price for a certain period of years.

"Gavi" means the Gavi Alliance, a non-profit foundation registered in the canton of Geneva, Switzerland, which has identified and from time to time updates a list of developing world countries that are eligible for Gavi support.

"Global Access Commitments" means the commitments stated in this Agreement and in the "Global Access" section of the Grant Agreement.

"Minimum TPP" means the currently agreed upon target product profile attached as Appendix B.

"Private Sector Markets" means those segments of a market other than Public Sector Markets.

"Product" means PnuVax's 13-valent pneumococcal conjugate vaccine containing the following serotypes; 1, 3, 4, 5, 6C, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F (PnuVax PCV-13).

"Public Sector Markets" means (a) governments including government ministries and agencies, together with government-funded institutions, such as hospitals and prison services; (b) NGOs including those recognized by the applicable local government ministry and UN-related organizations working for or in applicable countries, including the International Organization for Migration, UNICEF and PAHO; (c) not-for-profit organizations including Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross; and (d) funding mechanisms including GDF, UNITAID, UNFPA, PEPFAR, USAID, Global Fund, and WHO and agencies or governments based outside of a Designated Countries but who are supporting implementation or procurement to/for a Designated Country.

"Public Sector Price" means the price paid by the Public Sector Markets, as stated below.

"UNICEF" means The United Nations Children's Fund, an international, intergovernmental organization established by the General Assembly of the United Nations by resolution No. 57(1) of December 11, 1946 as a subsidiary organ of the United Nations.

"WHO Prequalification" or **"WHO PQ"** means the positive written advice provided by the World Health Organization to United Nations agencies of the acceptability of the Vaccine for purchase by United Nations agencies and the inclusion of the Vaccine on the list of pre-qualified vaccines for purchase.

All capitalized terms used but not defined in this Agreement will have the meanings stated in the Grant Agreement.

2. **Prompt and Broad Dissemination of Knowledge and Information**. Consistent with the "Publication" provisions of the Grant Agreement, the Company will use reasonable and diligent steps to submit for publication (in a customary and reasonable manner) information related to the clinical trial(s) under the Project, including:

   a. prospective registration of clinical trials on a WHO compliant clinical trial registry (e.g., www.who.int/ictrp), with final clinical trial results submitted for publication within 12 months from the completion date of the trial in accordance with WHO reporting guidelines and recommendations;

   b. submission for publication of the status of each clinical trial conducted under the Project on www.clintrials.gov within the earlier of 12 months of the completion date of each clinical trial or the date imposed or specified by applicable law; and

   c. submission for publication of final results of each clinical trial under the Project in applicable peer reviewed open access journals within 12 months from the completion date of the clinical trial. In the event of an inability to obtain peer reviewed publication, the Company will publish in a manner reasonably acceptable to the Foundation.

      For purposes of this Section 2, "completion date" of a trial will be considered the date of the last subject last visit.

3. **Data Sharing with the Foundation**. The Company will provide to the Foundation access to information as follows:

   a. in connection with any stage-gate review under the Grant or related to the Project, access to de-identified clinical trial subject data and information including relevant chemistry, manufacturing and control data regarding the Project including anticipated Product approval timelines;

b. upon the Foundation's reasonable request (no more frequently than quarterly), access to de-identified clinical trial subject data and information including relevant chemistry, manufacturing and control data regarding the Project including anticipated Product approval timelines; and

c. provide the information and documentation as contemplated in the Section 9 below.

4. **Diligence**. The Company will use reasonable and diligent steps to:

a. conduct Health Canada clinical trials specified in the IPDP to meet the Health Canada's requirements to obtain Health Canada approval and to meet the Minimum TPP, and keep the Foundation promptly informed of any information impacting the Product's ability to meet the Minimum TPP or that is otherwise deemed to impact the Project or timelines by three months or more;

b. obtain and maintain the regulatory and Project expertise to support the Company's clinical, regulatory and development plans including Developing Country plans and WHO PQ;

c. conduct the activities in the IPDP, meet specified timelines and criteria included in the IPDP, the IPDP timeline and/or criteria, and also keep the Foundation promptly informed of any information impacting Company's ability to meet the IPDP timelines or criteria by three months or more, with the understanding that the IPDP is an amendable document (by mutual agreement of the Company and Foundation) which may be amended depending on the circumstances as they arise; and

d. consider using WHO's joint regulatory review mechanism for clinical trial approvals in Designated Countries; provided, always that all regulatory activity decisions will be Company's sole responsibility.

5. **Scientific Advisory Committee**. The Company must form a Scientific Advisory Committee to provide regular input and make recommendations to the Company regarding the development of safe, efficacious and affordable Product to ensure licensure and WHO PQ. The Company will maintain sole responsibility for and discretion over member selection for and appointment to this Committee, and the Company will retain sole discretion and control over Product development. However, this Committee must include members that have experience in the following areas: conjugate vaccine manufacturing, conduct of vaccine clinical trials leading to licensure, vaccine development in the developing world and regulatory expertise in vaccines and that are independent of the Company and academic institutions or investigators involved in the funded clinical trials. The Foundation will have a participatory role on this Committee, but at no time will the Foundation have a majority role on this Committee. This Committee exists to provide advice to the Company only. Select members of this Committee at the discretion of the Scientific Advisory Committee may attend Health Canada and WHO meetings when appropriate based on their expertise.

6. **Manufacturing and Supply**.

a. **Supply of Product**. The Company must manufacture the Product in compliance with all laws and requirements applicable to the Company, including those put forth by Health Canada and WHO PQ, including cGMP regulations as appropriate to the stage of Product development.

b. **Obligation to Manufacture the Product**. The Company must use all reasonable and diligent efforts to manufacture, package, label, store and ship the Product in accordance with applicable supply agreements (i) in reasonably sufficient quantities to meet the requirements of Public Sector Markets in Designated Countries, as further specified below; (ii) in accordance with any applicable licenses, permits, certificates, certifications, privileges, immunities, notifications, exemptions, classifications, registrations, franchises, approvals, authorizations, orders and other similar rights, or any waivers of the foregoing, issued by any applicable regulatory authority, and all pending applications therefor or renewals thereof; (iii) in accordance with all applicable laws and requirements; and (iv) in accordance with the terms of this Agreement.

c. **Capacity Commitment**. The Company must maintain a manufacturing capacity sufficient to produce a minimum of 70 million doses of the Product per year starting one year following WHO PQ ("**Initial Capacity**").

d. **Capacity Commitment for the Public Sector**. The Company commits, for a period beginning one year following WHO PQ and continuing for the Term, to reserve 80% of its Initial Capacity on an annual basis for sales of the Product to the Public Sector Markets in Designated Countries ("**Initial Capacity Reserve**").

7. **Distribution and Public Sector Pricing**. As between the Parties, the Company will have the exclusive right to commercialize the Product, subject to the scope of the relevant license rights of the Company and the commitments in this Agreement.

a. **Public Sector Plan**. The Company must develop and execute a comprehensive strategy for the production and distribution of the Product to Public Sector Markets ("**Public Sector Plan**"). The Company must keep the Foundation reasonably informed of activities under this plan.

b. **Gavi AMC Participation**. The Company may participate in the Gavi AMC, and nothing in this Agreement will be deemed to affect that participation; provided however, the rights and obligations of the Parties under this Agreement, including the obligation of the Company related to the Public Sector Price, will be in addition to those rights and obligations of the Company if any, under the AMC.

i. **Public Sector Pricing**. In consideration of the funding by the Foundation under the Grant OPP1172539, the Company will implement the following volume-adjusted pricing approach for the Product with a ceiling price based on annual cumulative doses supplied for UNICEF procurement as follows:

Annual UNICEF Procurement Volume	Ceiling price per dose[1]
<10M	US$1.00
10-20M	US$0.90
20-40M	US$0.82
40-55M	US$0.63
55-70M	US$0.54
>70M	US$0.48

The Company may propose an adjustment to the ceiling prices at the time of scale-up for clinical manufacturing and commercial manufacturing and then no more than once every five years after commercial launch to adjust for inflation and actual increases or decreases due to currency fluctuations, efficiencies of scale and yield improvements;

provided, that any upward adjustment must not exceed the rate of inflation in Canada for pharmaceutical product inputs since the last adjustment date.

[1] For those LMIC countries that are not able to procure through UNICEF, the ceiling UNICEF price of $1 per dose would apply regardless of volume, subject to the adjustment process set forth above.

ii. The Public Sector Price includes all costs of packaging, temperature monitoring devices as required by WHO guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23) or any later revision, vaccine vial monitors, and delivery in accordance with INCOTERM FCA to the designated airport.

c. **Product Reports**. Following WHO PQ, the actual number of doses of Product procured by Gavi is made publically available by Gavi/UNICEF. The Company will provide additional Product Reports (defined below) more frequently than the annual reports required by the Grant Agreement, if requested by the Foundation. A "**Product Report**" is a report that includes the (i) the number of doses of Product produced by the Company for Public Sector Markets in Designated Countries; (ii) the total number of actual tenders for Product for Public Sector Markets in Designated Countries; and (iii) the number of doses of Product supplied by the Company to Public Sector Markets in Designated Countries.

8. **Global Access License**. For the purpose of achieving Global Access, the Company hereby grants the Foundation a nonexclusive, perpetual, non-terminable, worldwide, royalty-free, fully paid up license (with the right to sublicense) to make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform, display and otherwise dispose of the Funded Developments in connection with the development, manufacture and/or sale of the Product; provided, that the license to sell, distribute and import shall not include the right to sell, distribute or import the Product for therapeutic use after marketing approval in countries that are not Designated Countries ("**Global Access License**"). The Foundation will not exercise the Global Access License except on the occurrence of one or more of the following events:

i. Company fails to comply with the Global Access Commitments or commits a material breach of this Agreement or the Grant Agreement and fails to cure such breach or failure within 90 days after written notice of such breach or failure;

ii. Company fails to comply with the restrictions on the Company's use of funds received from the Foundation under the Grant Agreement;

iii. Company commits gross negligence, fraud or willful misconduct;

iv. Company makes a strategic decision to discontinue the Product development and/or commercialization of the Product that meets the Minimum TPP; or

Company ceases to conduct business in the ordinary course or institutes a dissolution, bankruptcy proceeding, or an assignment for the benefit of creditors; provided, that a restructuring proceeding shall not be deemed a trigger event as long as the Company is continuing to perform under this Agreement.

9. **Technology Transfer**. If the Foundation exercises its license following the occurrence of one or more of the events in Section 8, the Company will cooperate with the Foundation in good faith and upon receipt of reasonable compensation therefor to make available and transfer all intellectual property, technology, data and information relating to the Product that is reasonably necessary to enable the Foundation (or one or more entities of the Foundation's choosing) to continue the Product, and to enable the use, manufacture, sale, offer-for-sale, distribution, and other disposition of the Product. To the extent possible, the Company will continue to meet its

Global Access Commitments (including price and supply) until completion of all transfer activities associated with the Global Access License. The Company and Foundation will cooperate in good faith to transition the Product, including the manufacture, sale, offer-for-sale, distribution, and use of the Product to the Foundation or its selected entities.

10. **Option for Program Related Investment**. If the Company intends to enter into any agreement or arrangement to obtain equity or debt funding from one or more third parties in a private placement or other offering of securities at any time during the Term ("**Financing**"), the Company, as a condition to entering into such agreement or arrangement, will provide the Foundation with the opportunity, if the Foundation so elects in its sole discretion and if the Foundation determines it is necessary or desirable in furtherance of its charitable purposes, to participate in such financing round through a program-related investment, as defined in section 4944(c) of the U.S. Internal Revenue Code, on such terms as are acceptable to the Foundation and the Company. This option applies to each Financing that occurs during the Term regardless of whether the Foundation has participated in a prior Financing.

11. **Term**. The term of this Agreement starts on the Effective Date and, unless terminated earlier per the terms of this Agreement, will terminate ten (10) years following WHO PQ of the Product ("**Term**") or will terminate immediately in the event that a revised Global Access Agreement is agreed to and executed at a later time that is within the Term and that is intended to replace this Agreement.

12. **Representations, Warrants and Covenants**. The Company represents, warrants, and covenants to the Foundation:

a. **Project Diligence and Necessary Skill**. The Company will maintain the necessary expertise, personnel, facilities, and equipment to perform the Project and the obligations under this Agreement;

b. **Compliance with Laws**. In carrying out the Project, the Company will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property rights of any third party.

c. **Reliance**. The Company acknowledges that the Foundation is relying on the information the Company provided in reports and during the course of any due diligence conducted before the Effective Date and during the Term. The Company agrees that the Foundation may continue to rely on this information and on any additional information the Company provides regarding activities, progress, and Funded Developments.

d. **Licenses and Permits**. The Company currently holds (or will hold before the first commercialization of the Product) all necessary foreign, federal, state, local, and other governmental licenses, approvals, registrations and permits necessary to use, design, develop, produce, manufacture, offer-for-sale, sell, distribute, import and export the Product for use as contemplated by the Project and this Agreement, including any such requirements imposed by any Designated Countries.

e. **Records Compliance**. The Company will maintain, in accordance with and for the period required under applicable laws, complete and adequate records pertaining to the Product under cGMPs appropriate to the stage of Product development.

f. **No Conflict**. The Company will not enter any agreement or arrangement with any third party that will prevent the Company from performing or impair its ability to perform its obligations under this Agreement.

g. **IP Rights**. The Company already has and will continue to maintain all rights to all intellectual property (including rights in any patents, data, confidential information, know-

how or other proprietary right) required to commercialize (make, have made, sell, offer-for-sale, distribute, import, export and use as contemplated by the Project and this Agreement) the Product.

h. **Product Modification**. During the term, if any injunction or prohibition against the Company's use or other disposition of the Product by reason of infringement or misappropriation of a patent or other intellectual property right, or if in the Company's opinion the Product is likely to become the subject of a claim of infringement or misappropriation, the Company will, at its option and expense, either: (i) procure (by licensing or otherwise) the right to continue to make the Product, or (ii) replace or modify the Product so that it does not infringe or misappropriate but is equivalent or superior in terms of efficacy, quality and safety.

i. **No Disputes**. The Product (including its use and disposition as contemplated by the Project and this Agreement) are not the subject of any third party intellectual property claims and are not subject to any disputes with a third party. The Company will notify the Foundation of any claims or disputes that arise during the Term.

j. **Disqualification and Debarment**. The Company, its employees, its contractors, or its agents are not and will not be, at the time of performance of any activity contemplated by this Agreement, (a) disqualified or debarred by any governmental authority for any purpose pursuant to applicable law or regulation or threatened with any disqualification or debarment or (b) charged or convicted for conduct relating to the development or approval of, or otherwise relating to the regulation of, any product under any applicable law or regulation.

k. **Warranty**. The Product is or will be manufactured by the Company in conformity in all material respects with all applicable requirements of a vaccine for human use, including all express and implied warranties related thereto.

l. **Corporate**. The information the Company has provided to the Foundation regarding its corporate structure and ownership of PnuVax SL Biopharmaceuticals is true and correct. The Company has and will continue to maintain operational control of PnuVax SL Biopharmaceuticals. None of the shareholders of PnuVax SL Biopharmaceuticals have the right to have their shares or other ownership interests redeemed without the unanimous consent of all of the shareholders of PnuVax SL Biopharmaceuticals.

13. **Obligations in the Event of Acquisition**. If the Company and/or the Company's assets necessary to perform the Company's obligations under this Agreement are transferred to, sold, or acquired by a third party, including as a result of a Change in Control (any such transfer, sale or acquisition, including a Change in Control, is referred to herein as a "**Transfer**"), the Company will ensure that this Agreement and all of the Company's obligations under this Agreement are assumed by the purchaser, transferee, acquirer or successor in a written agreement reasonably acceptable to the Foundation. The Company must not grant to a third party any rights or enter into any arrangements that would prohibit, prevent, or otherwise restrict the Company or any purchaser, transferee, acquirer, or successor of the Company's assets or the Company from fulfilling its obligations under the Agreement. For purposes of this Agreement "**Change in Control**" means (i) the acquisition after the date of this Agreement, directly or indirectly, by any person or group of the beneficial ownership of securities of the Company possessing more than 50% of the total combined voting power of all outstanding voting securities of the Company; (ii) a merger, consolidation or other similar transaction involving the Company, except for a transaction in which the holders of the outstanding voting securities of the Company immediately prior to such merger, consolidation or other transaction hold, in the aggregate, securities possessing more than 50% of the total combined voting power of all outstanding voting securities of the surviving entity immediately after such merger, consolidation or other transaction; or (c) the sale,

transfer or other disposition (in one transaction or a series of related transactions) of all or substantially all of the assets of the Company related to this Agreement.

14. **Assignment**. Neither this Agreement nor any of the Company's rights or obligations under this Agreement may be assigned without the Foundation's prior written consent, which consent will not be unreasonably withheld, except that the Company may assign this Agreement without this consent to an Affiliate or successor in connection with its Change in Control; provided, that the Company's assignee must be bound by the terms of this Agreement and must assume all of the Company's obligations under this Agreement in a written agreement reasonably acceptable to the Foundation. For purposes of this Agreement, an "**Affiliate**" means an entity controlled by, controlling or under common control with the Company and includes any entity more than 50% of whose voting stock or participating profit interest is owned or controlled, directly or indirectly, by the Company and any entity that owns or controls, directly or indirectly, more than 50% of the voting stock of the Company.

15. **Amendments**. No modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

16. **Survival**. A Party's obligations under this Agreement will be continuous and survive expiration or termination of the Grant Agreement.

17. **Notices and Approvals**. Written notices and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the signature page, or as otherwise directed by the other Party.

18. **Severability**. Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

19. **Relation to Grant Agreement**. This Agreement constitutes a part of the Grant Agreement and is incorporated by reference into the Grant Agreement. The terms of this Agreement are in addition to, and supplement, the terms of the Grant Agreement.

[*Remainder of page left intentionally blank*.]

The Foundation and PnuVax have duly executed the Agreement as of the dates set forth below.

BILL & MELINDA GATES FOUNDATION

By: DocuSigned by: Trevor Mundel DD5444F322CE4A9...

Name: Trevor Mundel
Title: President, Global Health

Date: August 17, 2017

PNUVAX INCORPORATED

By: DocuSigned by: Donald Gerson F6BEF7E3F9B6475...

Name: Donald Gerson
Title: CEO

Date: August 17, 2017

APPENDIX A

Designated Countries

Gavi-Countries (eligible, transitioning and transitioned)

Afghanistan
Angola
Armenia
Azerbaijan
Bangladesh
Benin
Bhutan
Bolivia
Burkina Faso
Burundi
Cambodia
Cameroon
Central African Republic
Chad
Comoros
Congo, Dem Republic of
Congo Rep.
Côte d'Ivoire
Cuba
Djibouti
Eritrea
Ethiopia
Gambia
Georgia
Ghana
Guinea
Guinea Bissau
Guyana
Haiti
Honduras
India
Indonesia
Kenya
Kiribati
Korea, DPR
Kyrgyz Republic
Lao PDR
Lesotho
Liberia
Madagascar
Malawi
Mali
Mauritania
Moldova
Mongolia
Mozambique
Myanmar
Nepal
Nicaragua
Niger
Nigeria
Pakistan
Papua New Guinea
Rwanda
São Tomé e Príncipe
Senegal
Sierra Leone
Solomon Islands
Somalia
Sri Lanka
Republic of Sudan
South Sudan
Tajikistan
Tanzania
Timor Leste
Togo
Uganda
Ukraine
Uzbekistan
Viet Nam
Yemen
Zambia
Zimbabwe

APPENDIX A- Continued

LMIC or Lower-Middle Income Countries

Those countries defined as such by the World Bank Atlas method, which countries are currently defined as having a GNI per capita between US$1,025 and US$4,035.

Certain countries in this Appendix A may be subject to embargo restrictions at present or in the future. The Parties acknowledge that such restrictions could preclude one or both Parties' ability to include such countries in any efforts under this Agreement.

APPENDIX B

Minimum TPP

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*
Indication*	Immunization of infants and children against *Streptococcus pneumoniae* serotypes for the prevention of invasive disease Should cover at least 60% of the invasive disease isolates in the target region and must include serotypes 1, 5 and 14.	Prevention of community-acquired pneumonia and reduction of nasopharyngeal carriage of serotypes included in the vaccine	 WHO_PCV_TPP_2008.pdf
Target Population*	The vaccine is designed to prevent disease among children <5 years of age and in particularly be effective in those < 2 years of age.	The vaccine is designed to prevent disease among among unimmunized children and adults through indirect (herd) effect	
Target Countries	Gavi eligible countries and graduating countries	Gavi eligible countries, low and middle income countries as defined by the World Bank.	
Efficacy*	Non-inferiority to SOC The endpoints used in the primary analysis will be: – The percentage of subjects with IgG ≥ 0.35 µg/ml and – The serotype-specific IgG GMC ratios in comparison with a licensed PCV The endpoints in the secondary analysis will be: – OPA GMT ratios (comparison with licensed PCV) – Serotype-specific OPA RCD plots Evidence of boostability	Same	Immunogenicity should be demonstrated in accordance with WHO criteria, which are based on non-inferiority to a licensed pneumococcal vaccine as outlined in WHO Recommendations for the production and control of pneumococcal conjugate vaccines. (WHO Technical Report Series, No 977, 2013 and any subsequent published guidance).
Duration of Protection	Duration of protection should be a minimum of 5 years.	Lifelong	
Onset of Immunity	Immunity within 4 weeks after full immunization.	Immunity within 2 weeks after full immunization.	
Indirect (Herd)	Yes; will be evaluated after	Yes; will be evaluated after	Demonstration of reduced

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*
Protection	introduction, including direct impact on serotype specific nasopharyngeal carriage.	introduction, including direct impact on serotype specific nasopharyngeal carriage.	carriage highly desirable per WHO TPP
Safety*	Equal to SOC	> SOC	The safety and reactogenicity profile should be comparable to, or better than that of the currently licensed pneumococcal conjugate vaccine. Contra-indications should be restricted to known hypersensitivity to any of the vaccine components per WHO TPP.
Co-administration	Non-interference with Expanded Program on Immunization (EPI)	Same	There should be no clinically significant interaction or interference in relation to safety and immunogenicity with concurrently administered vaccines.
Presentation	IM Multi dose vial Liquid – no reconstitution.	IM Single autodisable syringe or single dose vial, and multi dose vials if required by the WHO. Liquid – no reconstitution.	The vaccine must be available in mono-dose or low multi-dose presentations. Mono-doses must be either a single dose vial or a auto-disable compact pre-filled device. Low multi-dose presentations must be formulated and labelled in compliance with WHO policy or guidance.
Dosing Schedule and Route of Administration*	3 doses / routine	1 dose	Vaccine scheduling must be compatible with national infant immunization programmes and consist of not more than 3 doses in the first

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*
			year of life. The first dose must be shown to be administrable at 6 weeks of life or earlier. Information on the need for booster doses may be desirable in the future to answer questions on herd immunity effects and persistence of protection per WHO TPP.
Vaccine Volume (cm^3 /dose)	0.5mL/dose	0.5mL/dose	Per WHO guidelines
Stability / Shelf Life	Stability at 2-8°C with a shelf life of at least 24 months and VVM attached	Thermostable, no refrigeration needed	
Product Registration Path	. WHO pre-qualification in accordance with Procedures for assessing the acceptability, in principle, of vaccines for purchase by GAVI and distribution by United Nations agencies (WHO/IVB/05.19).	Same and licensure by low middle income countries	
WHO Prequalification Date	2020	2019	
Primary Target Delivery Channel	Purchase by GAVI and distribution through UNICEF delivery channels into country vaccination infrastructure.	Purchase by GAVI and distribution through UNICEF delivery channels into country vaccination infrastructure. Direct purchase by other LMICs.	
COGS	$1 / dose	$0.5 / dose	

Additional Variables of Interest

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*
Special Populations	Children	HIV Positive children	Per WHO TPP
Is companion diagnostic needed for use?	No	No	N/A
Target Procurement Price	<$1 per dose	<$0.5 / dose	CoGs analysis performed 26JAN2017. Target procurement price subject to change depending on CoGs re-evaluation at time of product launch based on actual realized cost inputs.

BILL & MELINDA GATES foundation

Grant Proposal Narrative

Product Development

We appreciate your interest in submitting a proposal to the Bill & Melinda Gates Foundation and we thank you for working with us throughout the proposal process. Your designated foundation program officer will continue to work collaboratively with you as you prepare your proposal to help you understand the connection between the foundation's relevant program strategy and the proposed project, as well as to respond to any questions you might have over the course of this process. You are encouraged to communicate with your program officer to make sure that your efforts are aligned with the proposal requirements and that you are not expending unnecessary time or energy in this process.

Answer all of the questions in this Proposal Narrative template and submit it to your foundation program officer for review and collaborative discussion. Due to tax, legal, and reporting requirements, all proposals must be submitted in English. The proposal must be submitted in Word, as PDFs will not be accepted.

The product(s) you are seeking to develop and all related activities are your responsibility, regardless of any input or feedback provided by the foundation. The foundation will not review study protocols, regulatory submissions, clinical results, PD documents or other information submitted to the foundation for compliance with safety, regulatory or legal requirements. You acknowledge and agree that any activities by the foundation in funding your product development, including its review of documents and plans and providing feedback and input, does not modify your obligation to obtain all applicable legal, regulatory and ethical approvals for the activities being conducted.

General Information

Investment Title	PnuVax PCV-13 Development Through POC in Infants		
Requested Amount (U.S.$)	$29,423,549	**Investment Duration (Months)**	29
Total Project Cost (U.S.$)	$29,423,549		
Opportunity ID	OPP1172539		

Prospective Grantee/Vendor Information

Organization Legal Name[1]	PnuVax Incorporated		
Organization Doing Business as	PnuVax		
Primary Contact Name	Donald F. Gerson	**Mailing Address**	
Primary Contact Title	CEO	Street Address 1	134 Albert St.
Primary Contact Email	[redacted]	Street Address 2	
Primary Contact Phone	[redacted]	Street Address 3	
Feedback Contact[2]	Donald F. Gerson	City	Kingston
Feedback Email[2]	[redacted]	State / Province	Ontario
Authorized Signer Name	Donald F. Gerson	Zip / Postal Code	K7L3V2
Authorized Signer Title	CEO	Country	Canada
Authorized Signer Email	[redacted]		
Website (if applicable)	www.pnuvax.com		

[1] Legal Name will be used in the agreement and should match the name on the bank account that receives the grant funds (assuming fully executed agreement).
[2] Feedback Contact/Email: The full name and email of the contact whom foundation staff queries for various surveys.

Tax Status (if known and applicable) Refer to Tax Status Definitions	Foreign Non-Exempt Organization - Other	**Organization's Total Revenue for Most Recent Audited Financial Year (U.S.$)**	$1,737,403 CAN $1,336,464 USD (1.30 rate)
U.S. Employer Identification Number (EIN) (if applicable)	N/A		

Submission Information			
Date Submitted	13 July 2017	Submitted by same as above	No
Submitted by Contact Name	[redacted]	Submitted by Contact Email	[redacted]
Submitted by Contact Title	[redacted]	Submitted by Contact Phone	[redacted]

Proposal Details

The Foundation is prohibited from conducting or funding any lobbying or political campaign activities, as these terms are specifically defined under U.S. tax law. Unlike many of our grantees/vendors who may engage in limited lobbying, the Foundation cannot lobby or fund any lobbying activities carried out by its grantees/vendors. We request that you please review the information at the following link: Foundation Funds and Advocacy, to assess whether any of your proposed activities may constitute lobbying as defined by the IRS. If so, you should revise your proposal accordingly prior to submission.

1. Executive Summary

Provide a high-level 1-2 paragraph summary of the entire investment.

Note: You will provide greater detail about the drug or vaccine product development component of this grant in the Integrated Product Development Plan (IPDP), not here.

PnuVax holds unique patent-protected technology that enables the rapid and non-toxic production of pneumococcal conjugates at high yields and in fewer processing steps than by traditional methods, resulting in a reduced Cost of Goods for use in preparing a low-cost 13-valent childhood pneumonia vaccine for developing countries.

Evaluation of PnuVax PCV-13 in animals has demonstrated that PnuVax PCV-13 is immunogenic and protective in animals through per-serotype IgG and OPA levels evaluated during previous work.

The current project proposes that;

i) clinical trial lots of PnuVax PCV-13 be manufactured and characterized in accordance with Health Canada requirements,

ii) clinical trial lots be evaluated in Canada under regulation by Health Canada via a Phase 1 safety study in adults, and

iii) clinical trial lots be evaluated in Canada under regulation by Health Canada via a Phase 2a Proof of Concept (POC) study in infants,

to obtain preliminary data surrounding the immunogenicity (IgG) and functional protection (OPA) of PnuVax PCV-13 in humans.

Describe the charitable purpose of this work by completing the statement "This grant will be used [to …]." Please limit to one sentence, begin with "to" and do not include a period at the end. Example: "This grant will be used [to fund new schools and assist other organizations in the design of new schools]"

This grant will be used toward the aim of increasing the availability of low-cost PCV-13 to the developing world.

2. How We'll Work Together

This question is intended to begin the dialogue on how foundation staff would work with you to achieve the intended outcomes. Topics could include minimal staff support, any specific issues that would likely need on-going discussion, regular communications, or other information to help establish mutual expectations and assist with implementing the proposed work.

PnuVax has a high-efficiency culture, and will work expeditiously to launch its PnuVax PCV-13 pneumococcal conjugate vaccine for children worldwide. PnuVax and the Foundation share the goal of preparing high-volumes of low-cost PCV-13 as soon as possible.

PnuVax welcomes and encourages ongoing visits by Foundation members and their consultants to Montreal, to maximize Foundation involvement and ultimately the project's success.

PnuVax also looks forward to monthly scheduled calls with their project Program Officer during this project, and additional calls as needed.

Given the significant scope of the proposed work, PnuVax has budgeted for travel to Seattle for in-person meetings with the Foundation and PATH.

As agreed to by PnuVax and PATH, PATH will be subcontracted by PnuVax to provide ongoing clinical trial protocol support to PnuVax during the clinical trial phases of this project, including clinical trial protocol review, Health Canada package review so as to help ensure critical questions are posed in writing to Health Canada by PnuVax, and also to review meeting minutes generated from formal

interactions between PnuVax and Health Canada.

Further, PATH will also provide overall additional clinical trial guidance related to obtaining WHO PQ for PnuVax PCV-13, which although beyond the scope of the currently proposed project, should be considered in parallel to ensure the trials performed during this project align with the path to meeting the WHO TPP. Through doing so, it may also be possible to minimize the subsequent trials required beyond the trials needed to obtain Health Canada licensure for PnuVax PCV-13 (if any), which would further reduce the time and cost to product launch.

3. Geographic Areas to Be Served

List all countries and sub-regions/states that would benefit from this work and associated dollar amounts. If areas to be served include the United States, indicate city and state. Add more rows as needed. More information about Geographic Areas to Be Served can be found here.

Location	Foundation Funding (U.S.$)
World	$29,423,549

4. Geographic Location of Work

List all countries and sub-regions/states where this work would be performed and associated dollar amounts. If location of work includes the United States, indicate city and state. Add more rows as needed. More information about Geographic Location of Work can be found here.

Location	Foundation Funding (U.S.$)
Canada	$25,941,774
Candler, North Carolina, United States	$3,145,000
Seattle, Washington, United States	$336,775

5. Global Access and Open Access

In order to establish that the projects we fund are charitable and will have a positive impact on the intended beneficiaries of our work, the foundation requires the projects it funds be conducted and managed in a manner that ensures Global Access and Open Access.

"Global Access" is a foundation policy requiring that: (a) the knowledge and information gained from the project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the project.

"Funded Developments" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the project, including modifications, improvements, and further developments to Background Technology.

"Background Technology" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the project used as part of the project.

Additional information about Global Access (including examples and case studies) can be found at http://globalaccess.gatesfoundation.org/.

"Open Access" is a foundation policy that sets the requirements, terms and conditions for publication of Funded Developments in a peer-reviewed journal. Additional Information on the foundation's Open Access Policy for peer-reviewed publications and underlying data can be found at www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy. Note: the foundation will pay directly for reasonable fees to effect publication on "open access" terms; such fees should not be included in the project budget (See the Open Access Policy FAQs for further detail).

a) Knowledge and Information

Describe how the knowledge and information gained from the project will be promptly and broadly disseminated (including how you will comply with the foundation's Open Access Policy, discussed above).

PnuVax is committed to Global Access, through its ongoing efforts to develop and manufacture a low-cost pneumococcal conjugate vaccine for distribution to developing countries.

Specifically, there are two major forms by which the information generated during this project will be disseminated. The first relates to publications outlining the results of the clinical studies. The second relates to Health Canada documentation that will be generated and publically released by Health Canada to summarize the test product(s) and clinical trial results generated for PnuVax PCV-13.

PnuVax will comply with the Foundation's Open Access Policy by adhering to the data access and publication mechanisms detailed in their Global Access Agreement with the Foundation.

b) Funded Developments (Indicate "not applicable," as appropriate)

i. **Describe any Funded Developments that may ultimately result from the project, including any Background Technology that will be used or incorporated in the proposed project. If applicable, briefly explain how the Funded Developments will be made available and accessible at an affordable price to the intended beneficiaries. The use of commonly-available, off-the-shelf products (such as Microsoft Excel, Adobe, etc.) need not be disclosed.**

No Funded Developments are anticipated as a result of completing this upcoming project. Ultimately, the Funded Development will be the Product PnuVax PCV-13. This project will use Background Technology related to PnuVax's already existing IP, as listed in PnuVax's Intellectual Property (IPP) Report. This Background Technology applies to PnuVax's unique conjugation methodology.

ii. **Please confirm that you will make the Funded Developments – including any Background Technology incorporated into or required to use the Funded Developments – available to achieve the proposed project's goals and Global Access. If you foresee any obstacles to achieving Global Access (e.g., third party rights, broad access, time frame, affordability) please briefly summarize the obstacles and the specific steps that you will take to address them.**

PnuVax Inc. has already made, and commits to continue to make, their Background Technology available for use to achieve the proposed project outcomes and to comply with the Global Access Agreement. PnuVax is committed to achieving Global Access to their pneumococcal conjugate vaccine through eventually manufacturing PnuVax PCV-13 and delivering PnuVax PCV-13 to Unicef for distribution to developing countries assuming the Product is purchased. We do not foresee any obstacles to achieving the proposed project goals or to achieving Global Access.

c) If one or more of the following applies, please click the following link to complete an Intellectual Property (IP) Report:

- Creation of Funded Developments will likely involve new IP rights (Note: copyrights in works intended to be published in accordance with the Open Access Policy need not be disclosed);
- Use of Background Technology requires access to existing IP rights; or
- For-Profit entities are engaged in the project.

Note: For login purposes, please use the email address to which this Proposal Narrative was sent. To delegate permissions to another member of your project team, or for any questions regarding the IP Report, please contact GlobalAccess@gatesfoundation.org.

6. Advocacy and Lobbying

US law prohibits foundation funds from being earmarked to support direct or grassroots lobbying communications. Describe how you will conduct this project in compliance with these rules, as summarized in the Advocacy Guidelines Handout, and any other relevant local, state, or non-US lobbying laws. If foundation grant funds will be earmarked to influence policies, budgets, innovations, frameworks, action plans, etc., that could require a legislative vote, please explain how such "legislative" activities will be conducted in accordance with the applicable rules and exceptions. Your explanation should address both direct and grassroots communications. If this does not apply, please indicate N/A.

N/A. No grant funds will be used for advocacy or lobbying activities.

7. Conduct and Control of the Project [Complete if Global Health or Global Development Applicant]

1. **Please confirm that your organization:**

a) **will maintain the expertise necessary to conduct, control, manage, and monitor all aspects of the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards and policies and is responsible for determining and complying with these requirements and standards;**
b) **will not disclose any confidential or protected information to the Foundation without obtaining prior written approval from the foundation and all necessary consents to disclose such information;**
c) **acknowledges that any activities by the Foundation in reviewing documents, providing input or funding does not modify your organization's responsibility for determining and complying with all applicable ethical, legal, regulatory, and safety requirements for the Project in all places;**
d) **will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted standards and as required by law (for instance, general, professional, clinical trial, product liability, medical malpractice, workers' compensation, or otherwise);**
e) **will not transfer any biological materials, chemicals, reagents, hazardous materials or the like to the Foundation.**

Confirmed X

Not confirmed ____ (please explain)

N/A

2. **Does the Project involve any of the following: clinical trial, other trial involving human subjects, post-approval study, experimental medicine, genetically modified organism, or the provision of medical/health services?**

No ____

Yes X (If yes, please list all approvals and consents required for each site and describe the timeframe in which your organization will acquire the necessary approvals and consents.)

This project incorporates human clinical trials. The Phase 1 study will require adult participants, and the Phase 2a POC study will require infant participants. PnuVax will seek approval from Health Canada to perform the planned human studies. PnuVax's clinical collaborator OHRI (Ottawa Hospital Research Institute) will collect consent from all study volunteers prior to their participation in the planned human studies.

Phase 1 clinical trial approval from Health Canada will be sought in Q12018. Participant consents will be obtained prior to dosing each participant in the Phase 1 trial.

Depending on the outcome of the Phase 1 trial, PnuVax will seek clinical trial approval for the Phase 2a POC infant study in 2018. Guardian consent for infant participants will be obtained prior to any and all dosing involved in the Phase 2a trial.

3. **Please identify the name of the entity that will be the sponsor/responsible party of any clinical trials, studies involving human subjects, experimental medicine studies, post-approval studies, products, or regulatory filings contemplated by the Project. Note that the Foundation will not serve as the sponsor/responsible party nor accept delegation of any of these responsibilities. If the Project will not involve such activities, please indicate not applicable or N/A below.**

Regulatory Sponsor: PnuVax Incorporated (Principal: Dr. Donald F. Gerson)

Clinical Trial Sponsor: Ottawa Hospital Research Institute (OHRI) (Principal: Dr. D. William Cameron)

8. Organizational Capacity

Describe any changes or improvements you plan to make to your organization's capacity to undertake or achieve the outcomes of the proposed investment.

Through its captive CMO PnuVax SL Biopharmaceuticals, Inc., PnuVax plans to increase available qualified personnel to staff this project once the required funding is available to do so. The hiring plan will see the total FTE count increase to up to 32 FTEs in 2017, then up to 47 FTEs in 2018, and finally up to 55 FTEs in 2019 to support the scope of this proposed project.

Indirect cost projections for Q32017 onward attributable to PCV-13 development have been provided to the Foundation. These indirect costs already include the increased administrative and accounting staff that will be needed to manage this proposed investment. PnuVax SL Bio will hire these required additional staff once the grant is awarded.

9. Organizational Fit

What experience does your organization have to implement the proposed work?

PnuVax has direct experience in developing and manufacturing licensed pneumococcal conjugate vaccine (PCV), as the PnuVax principals were directly responsible for the launch and approval of Prevnar7 at Wyeth-Lederle. Dr. Donald F. Gerson also oversaw the development and manufacture of the first licensed meningococcal conjugate vaccine (MCV) and the first haemophilus B (HiB) conjugate vaccine.

Through support from the previous Foundation grants, product development of PnuVax PCV-13 is already well underway. To date, PnuVax Inc. has already prepared multiple lots of investigational 13-valent pneumococcal conjugate vaccine (PnuVax PCV-13, PnuVax) that are comparably immunogenic (IgG) and protective (OPA) to the currently licensed 13-valent PCV (Prevnar13, Pfizer).

Through clinical collaboration with the Ottawa Hospital Research Institute (OHRI), PnuVax has already largely organized its clinical trial protocols and trial sites. PnuVax has also already met with Health Canada regarding their clinical trial plans. By partnering with the OHRI, PnuVax will have the trials conducted at one of Canada's leading clinical research institutes. Dr. Bill Cameron, Medical Director for Clinical Research at the Ottawa Hospital Research Institute, will harness the extensive investigator and trial site network in Canada known as CIRN (Canadian Immunization Research Network). This includes, but is not limited to, working with Dr. Scott Halperin (Director of the Canadian Center for Vaccinology) who was directly involved in running previous Prevnar trials and is an expert in the investigation of conjugate vaccines and infant co-administration compatibility of conjugate vaccines.

The recent independently performed Cost of Goods (CoGs) analysis performed for PnuVax PCV-13 estimated that PnuVax PCV-13 could be readily manufactured and sold for $1/dose or lower. This is in line with PnuVax's priority of delivering high volumes of quality PCV to the developing world at low cost.

Through PnuVax's captive CMO PnuVax SL Biopharmaceuticals, Inc. (a Canadian Controlled Private Corporation), PnuVax has the cGMP manufacturing facility required to manufacture PnuVax PCV-13 for evaluation in humans. Facility direct costs included in the budget will significantly ameliorate this project, as they will rise based on the increased facility used required to prepare clinical trial lots.

PnuVax's regulatory preparations are also well underway, as described in the IPDP. Health Canada approval will be sought for the clinical trials encompassed by the proposed project. PnuVax has already held a preliminary meeting with Health Canada regarding their PCV. PnuVax has also initiated WHO contact regarding the pathway to WHO PQ. PnuVax's large-scale manufacturing facility already has large-scale Level 2 Biosafety certification from Health Canada, one of only two facilities to obtain such approval in Canada. PnuVax cGMP systems are either already in place on site or are ready to be initiated on site, appropriate to the stage of development of PnuVax PCV-13. A cGMP establishment license is not required to perform this project. Rather a cGMP license is only needed once large-scale commercial production begins on site, which is well beyond the scope of this project. However, with moving toward cGMPs in mind, all product development has been thoroughly documented to date and performed in accordance with cGMPs appropriate to the stage of product development. PnuVax principals Drs. Donald F. Gerson and M. Gail Meadows are worldwide experts in CMC and Quality aspects of the manufacture and launch of conjugate vaccines, and PnuVax will follow a similar approach to obtaining approval for PnuVax PCV-13 as that which they successfully performed while at Wyeth for Prevnar in 2000.

PnuVax SL Bio will manufacture purified polysaccharide and carrier protein in-house for purchase as supplies (APIs) for use in subsequent conjugation and vaccine formulation activities. PnuVax personnel are well versed in product development, experimental design, and systematic optimization techniques directly applicable to this project.

This project will help complete product development and clinical trials required to obtain preliminary human results for PnuVax PCV-13. With continued support, PnuVax can progress rapidly and is ready to begin this project immediately.

The overarching objective of PnuVax is to quickly develop, launch, and manufacture low-cost PCV-13 for the developing world. Combined with the progress already made to date and the facilities and clinical collaborations available to PnuVax, our organization is uniquely positioned to not only complete the proposed PCV product development and human trials, but to also later manufacture product under cGMPs in quantities that could significantly impact Global Health.

10. Beneficiaries

Who would benefit from this investment?

The PnuVax PCV-13 Product that will eventually be launched as a result of the current PnuVax PCV-13 program will be manufactured by PnuVax for distribution through the GAVI/UNICEF system to children in developing countries worldwide.

11. Data Access

We anticipate this investment, if funded, would generate datasets that may be of interest to the foundation and/or to the field if made publicly available. Please describe any datasets that will be generated as part of this investment. Specifically address when and how the datasets would be made available to the foundation and/or to the public, in what form or format, and any anticipated costs to your organization. Additional information about Data Access can be found here.

Datasets will be generated from the clinical studies planned as the second and third dimensions of this project.

Specifically, a Phase 1 adult clinical trial dataset will be generated from the Phase 1 Safety study, and a Phase 2a infant clinical trial dataset will be generated from the Phase 2a infant Proof of Concept (POC) study.

De-identified subject data from the clinical studies will be made publically available in accordance with the Foundation's Open Access Policy as agreed to in PnuVax's Global Access Agreement.

Funding is not provided to achieve dataset access.

12. Election Related Activities

N/A

Budget Narrative

The purpose of the budget narrative is to supplement the information provided in the excel-based budget template by justifying how the budget cost elements are necessary to implement project activities and accomplish target outcomes. The budget narrative is a tool to help foundation staff fully understand the budgetary needs of the project and is an opportunity to provide descriptive information about the costs, drivers, and risks that can't be easily communicated in the budget template. Together, the budget narrative and budget template should provide a complete quantitative and qualitative description that supports the proposed budget. The description provided in the budget template should be very brief. Please use this budget narrative to provide a thorough description of your budget and only complete questions that are relevant to your grant proposal.

For Global Development, Global Health and Global Policy and Advocacy related grants: If your proposal includes any sub-contracts and/or sub-grants greater than $1 million USD, please complete a separate budget template and narrative for each organization.

For U.S. Programs, Communications and Family Interest related grants: If your proposal includes any sub-contracts and/or sub-grants greater than $250,000 USD, please complete a separate budget template and narrative for each organization.

1. Summary

Please explain the major cost drivers and how costs relate to planned activities and target outcomes. Also explain any potential risks in spending as budgeted and any plans to mitigate those risks.

If budgeting by outcomes, or additional dimension, please explain the major cost drivers per outcome or other relevant dimension.

PnuVax Incorporated will use PnuVax SL Biopharmaceuticals, Inc. on a sub-contract basis to perform the project. This will occur in an identical fashion to PnuVax's previous grants received from the Foundation. This subcontracting arrangement is low risk, as PnuVax Inc. has already successfully used PnuVax SL Bio twice to complete all milestones related to their two previous grants.

PnuVax Inc. plans to provide a $29,423,549 USD sub-award to PnuVax SL Biopharmaceuticals, Inc. on a sub-contracting basis only. Funds will only be used to perform the project. Funding from the Foundation will not be used toward any Prohibited Activities over the life of the grant, including any extensions.

Work will be performed by PnuVax SL Bio on a sub-contract basis, alongside relevant other sub-contractors in which case PnuVax SL Biopharmaceuticals will serve as a pass-through to the multiple listed individual sub-contractors (e.g. Ottawa Hospital Research Institute, PATH, Queen's University, etc).

Overall, the major cost drivers of the project are broken down as follows;

1. Total FTEs: 38.0% of grant total without indirect costs.
2. Total Travel: 0.2% of grant total without indirect costs.
3. Total Consulting: 0.0% of grant total without indirect costs.
4. Capital Equipment: 6.1% of grant total without indirect costs.
5. Other Direct Costs (Supplies & Direct PCV Facility Costs): 20.9% of grant total without indirect costs.
6. Sub-awards (Sub-contracts only): 34.8% of grant total without indirect costs.
7. Indirect Costs (Overheads): 8.8% of grant total without indirect costs.

Summary by Expense Category

Category						TOTAL	% of Total Direct Cost
Personnel	$ 1,275,910	$ 4,199,455	$ 4,790,760	$ -	$ -	$ 10,266,126	38%
Travel	16,800	22,950	17,850	-	-	57,600	0%
Consultants	-	-	-	-	-	-	0%
Capital Equipment	1,055,000	600,000	-	-	-	1,655,000	6%
Other Direct Costs	1,812,164	2,063,055	1,785,595	-	-	5,660,814	21%
Sub-awards	1,288,959	4,114,355	3,993,127	-	-	9,396,441	35%
TOTAL DIRECT COST	**5,448,834**	**10,999,815**	**10,587,331**	**-**	**-**	**27,035,980**	**100%**
Indirect Cost	481,191	971,402	934,976	-	-	2,387,569	9%
TOTAL BUDGET	**$ 5,930,025**	**$ 11,971,218**	**$ 11,522,307**	**$ -**	**$ -**	**$ 29,423,549**	**109%**

Major cost direct cost drivers for each of the major dimensions for this project are as follows:

Breakdown along Additional Dimension

						TOTAL	% of Total Direct Cost
Preclinical	$ 4,857,716	$ 4,666,171	$ -	$ -	$ -	$ 9,523,888	35%
Phase 1	276,700	4,439,948	1,065	-	-	4,717,713	17%
Phase 2	-	764,394	9,236,635	-	-	10,001,029	37%
Direct Facilities Costs	314,417	1,129,302	1,349,632	-	-	2,793,351	10%
N/A	-	-	-	-	-	-	0%
TOTAL DIRECT COST	**5,448,834**	**10,999,815**	**10,587,331**	**-**	**-**	**27,035,980**	**100%**

Dimension 1. Preclinical: This dimension is one of the two major cost drivers of the overall project.

The greatest cost driver within this outcome is the labor needed to perform the significant work associated with successfully completing this stage of the project.

The other major cost driver of this dimension is direct costs for the needed physical supplies such as reagents and consumables, together with highly specialized materials required to prepare clinical trial doses for adults and infants. Supplies include PS, CRM, processing supplies such as filters and clarifiers, and specialty glassware.

A moderate cost driver of achieving this dimension is the project-specific equipment needed for this project, including an additional seed fermentor, a flow cytometer, a protein analyzer, an additional HPLC unit customized for use with conjugated PSs, the rate nephelometry unit, a clinical lot finishing unit, the larger-scale conjugation unit, and the NMR unit. PnuVax has carefully considered the basic equipment needs for achieving this milestone (dimension), and together with equipment purchased by PnuVax during previous grants, the budget allows for the needed preparatory and analytical instrumentation to be purchased upfront.

There is also a moderate amount of sub-contracting work required, therefore PnuVax SL Bio will use various companies on a sub-contract basis to perform independent vaccine sterility assaying, critical aseptic operations including filling and finishing activities for the syringe clinical doses of PnuVax PCV-13, and independent potency assaying of PnuVax PCV-13 Drug Substance and Drug Product retain samples.

Budgeted indirect costs related to this dimension are attributed to the unavoidable costs realized by PnuVax SL Bio to run their Montreal facility and equipment, and under cGMPs appropriate to the stage of development, to allow for the APIs, Drub Substances, Drug Product, and finished clinical trial doses of PnuVax PCV-13 to be manufactured, characterized, documented, and formally released to OHRI for human studies.

Costs for travel are minimal, as PnuVax incorporates a high efficiency approach to communication and only holds off-site in-person meetings when necessary. Off-site activities during this dimension are expected to be limited to audits of fill and finish facilities, auditing serology arrangements (IgG, OPA), and updating the Foundation as needed in Seattle. PnuVax also encourages the Foundation to visit them in Montreal anytime.

Dimension 2. Phase 1: This dimension is a moderate cost driver of the overall project.

The greatest cost driver within this dimension is sub-contracting, followed by labor. Sub-contracting costs realized for this dimension will be largely attributed to the Ottawa Hospital Research Institute (OHRI) as this organization will be conducting the Phase 1 human study in adults encompassed by this dimension. Labor associated with achieving this milestone is significant and will be ongoing during the course of the study as well as during the characterization of sera obtained from the study participants.

Costs for travel have been minimized to trips to Ottawa required for clinical collaboration and interactions with Health Canada, together with serology meetings (IgG, OPA) once Phase 1 samples have been obtained and sent for analyses, and updating the Foundation as needed in Seattle. PnuVax also welcomes the Foundation to visit them in Montreal anytime.

Dimension 3. Phase II POC: This dimension is the other major cost driver of the overall project.

Labor is anticipated to be a major cost driver of this dimension based on the significant preparation required for initiating the trial. The other major cost driver for this dimension is the cost of sub-contracting the Phase 2a (POC) clinical study in infants to the OHRI and then performing the corresponding serology (IgG, OPA) also on a sub-contract basis.

Risks: Risk related to unforeseen changes occurring in the budget are low, as PnuVax has used actual costs realized during work performed during the previous two grants to budget for work in the proposed project. As such, it is highly unlikely that the actual costs will significantly vary from the budgeted amounts.

Because the number of patients included in each trial will be determined as part of this project and is subject to change depending on Health Canada meeting outcomes, the least concrete budgeted costs are those listed to perform the clinical trials and the associated serological analyses. However, while there may be slight variations in the actual costs to perform the trials and serology that are beyond PnuVax's control, PnuVax has minimized the risk of budget drift related to these tasks by accounting for inflation in the currently quoted costs, and using the proposed project schedule to estimate cost realization dates in the budget.

The other cost category that can sometimes be difficult to predict is required labor. However, during previous grants, PnuVax has remained within budget in all cost categories, and so there is minimal risk that there will be significant deviations from the proposed labor allocations.

2. Personnel and Benefits

Personnel: Provide a brief explanation of personnel budgeted, including responsibilities as they relate to the grant. Also include assumptions made for any staff budgeted which are to-be-hired, including salary estimates for these personnel.

PnuVax Inc will sub-contract the labor for this project to PnuVax SL Bio. PnuVax SL Bio FTEs will perform the project-specific labor required to achieve the project milestones culminating in evaluating Phase 2a POC clinical trial data from PnuVax PCV-13 in infants.

It is recognized that work related to the Phase 2b pivotal clinical trial(s) in infants, product scale-up and manufacturing for licensure, product registration and commercialization, product WHO prequalification, product launch, and initiation of sales, are all beyond the scope of the current proposed project. Therefore, additional personnel will be hired beyond this project to achieve product commercialization and launch.

The following hiring plan has been developed to ensure that Phase 2a POC infant data can be obtained and evaluated, with sufficient and appropriate personnel available.

Total Personnel Hiring Plan:

Overall Hiring Plan	2017 Actual	2017 Forecasted	2018 Forecasted	2019 Forecasted
Intake 1 (MAY 2017)	9			
Intake 2 (JUN 2017)		2		
Intake 3 (JAN 2018)			15	
Intake 4 (JAN 2019)				8
Total Headcount	**30**	**32**	**47**	**55**

Hiring Plan Personnel Category Breakdown:

Category Breakdown	Intake 1	Intake 2	Intake 3	Intake 4
Graduate Engineers	2		2	
Engineers			5	4
Graduate Scientists			1	
Scientists			1	
Technical Officers			2	

Technicians	7	2	4	4
Total FTEs	**30**	**32**	**47**	**55**

The following list of personnel only includes FTEs that are directly attributable to the project, and does not include any administrative staff that will be used to perform standard organizational operating activities such as accounting, payroll, and procurement activities. No performance-based incentives exist at PnuVax SL Bio.

Where a name is either likely to change or is yet to be determined based on pending upcoming hires if the grant is approved, a position title has been included instead of the FTE's first and last names. Key personnel and/or positions (with grant responsibilities) together with the associated billable labor rates to execute this project are as follows.

Name/Position	Responsibilities	Labor Rate (USD/hr)
Donald Gerson	Operations Head - Manufacturing of clinical doses, characterization of clinical doses, test product head, Submissions sponsor, WHO, GAVI point of contact.	$139
[redacted]	[redacted]	$91
[redacted]	[redacted]	$60
[redacted]	[redacted]	$60
[redacted]	[redacted]	$52
[redacted]	[redacted]	$52
[redacted]	[redacted]	$39
[redacted]	[redacted]	$33
Conjugation Tech 1	Conjugation Technician - Responsible for performing conjugations and characterization activities related to clinical trial Drug Substance preparation.	$33
Conjugation Tech 2	Conjugation Technician - Responsible for performing conjugations and characterization activities related to clinical trial Drug Substance preparation.	$33
Fermentation Tech 1	Fermentation Technician - Responsible for performing fermentations required to prepare clinical trial polysaccharides and carrier protein.	$33
Engineer 1	Purification Engineer - Responsible for overseeing pneumococcal polysaccharide purification activities.	$47
Engineer 2	Purification Engineer - Responsible for overseeing carrier protein purification activities.	$47
Engineer 3	Conjugation Engineer - Responsible for aiding Conjugation Lead in ongoing conjugation optimization and scale-up activities.	$33
Engineer 4	Formulation Engineer - Responsible for performing formulation studies to evaluate excipient stability and adjuvant preparation/procurement, adjuvanting procedures, and aluminum content.	$33
[redacted]	[redacted]	$39
[redacted]	[redacted]	$47
Purification Tech 1	Purification Technician - Responsible for performing ongoing pneumococcal polysaccharide purification activities.	$33
Purification Tech 2	Purification Technician - Responsible for performing ongoing pneumococcal polysaccharide purification activities.	$33
Purification Tech 3	Purification Technician - Responsible for performing ongoing carrier protein purification activities.	$33
Purification Tech 4	Purification Technician - Responsible for performing ongoing carrier protein purification activities.	$33
Conjugation Tech 3	Conjugation Technician - Responsible for performing conjugations and characterization activities related to clinical trial Drug Substance preparation.	$33
Conjugation Tech 4	Conjugation Technician - Responsible for performing conjugations and characterization activities related to clinical trial Drug Substance preparation.	$33
Conjugation Tech 5	Conjugation Technician - Responsible for performing conjugations and characterization activities related to clinical trial Drug Substance preparation.	$33
Conjugation Tech 6	Conjugation Technician - Responsible for performing conjugations and characterization activities related to clinical trial Drug Substance preparation.	$33
Assay Tech 1	Assay Technician - Polysaccharide characterization assays.	$33

Assay Tech 2	Assay Technician - Polysaccharide characterization assays.	$33
Assay Tech 3	Assay Technician - Carrier protein characterization assays.	$33
Assay Tech 4	Assay Technician - Conjugate characterization assays.	$33
Assay Tech 5	Assay Technician - Conjugate characterization assays.	$33
Microbiology Tech 1	Microbiology Technician - Responsible for facilitating aseptic operations, water quality monitoring, pneumococcal strain identification/assaying, environmental monitoring, critical sterility testing of raw materials, intermediates, Drug Substances, and Drug Products.	$33
Microbiology Tech 2	Microbiology Technician - Responsible for facilitating aseptic operations, water quality monitoring, pneumococcal strain identification/assaying, environmental monitoring, critical sterility testing of raw materials, intermediates, Drug Substances, and Drug Products.	$33
Process Engineer 1	Process Engineer - CMC moderator.	$33
Process Engineer 2	Process Engineer - Polysaccharide process.	$33
Process Engineer 3	Process Engineer - CRM process.	$33
Process Engineer 4	Process Engineer - Conjugation process.	$33
Process Engineer 5	Process Engineer - Formulation process.	$33
Quality Engineer 1	Quality Engineer - Process validation, aid in preparation of CTAs.	$33
Quality Engineer 2	Quality Engineer - Assay validation, aid in preparation of CTAs.	$33
Fermentation Tech 2	Fermentation Technician - Responsible for performing fermentations required to prepare clinical trial polysaccharide and carrier protein broth.	$33
Fermentation Tech 3	Fermentation Technician - Responsible for performing fermentations required to prepare clinical trial polysaccharide and carrier protein broth.	$24
Fermentation Tech 4	Fermentation Technician - Responsible for performing fermentations required to prepare clinical trial polysaccharide and carrier protein broth.	$24
Purification Tech 5	Purification Technician - Responsible for performing ongoing pneumococcal polysaccharide purification activities.	$24
Purification Tech 6	Purification Technician - Responsible for performing ongoing carrier protein purification activities.	$24
Quality Tech 1	Quality Technician - Responsible for assay validation activities. Aid in preparation of CTAs.	$24
Microbiology Tech 3	Microbiology Technician - Responsible for facilitating aseptic operations, water quality monitoring, pneumococcal strain identification/assaying, environmental monitoring, critical sterility testing of raw materials, intermediates, Drug Substances, and Drug Products.	$24
Microbiology Tech 4	Microbiology Technician - Responsible for facilitating aseptic operations, water quality monitoring, pneumococcal strain identification/assaying, environmental monitoring, critical sterility testing of raw materials, intermediates, Drug Substances, and Drug Products.	$24
Assay Tech 6	Assay Technician - Potency assays.	$33
Assay Tech 7	Assay Technician - Serological assays.	$33
Quality Engineer 3	Quality Engineer - Process validation, aid in preparation of CTAs.	$33
Quality Engineer 4	Quality Engineer - Assay validation, aid in preparation of CTAs.	$33
Quality Tech 2	Quality Technician - Responsible for process validation activities, aid in preparation of CTAs.	$24
Quality Tech 3	Quality Technician - Responsible for process validation activities, aid in preparation of CTAs.	$24
Microbiology Tech 5	Microbiology Technician - Responsible for facilitating aseptic operations, water quality monitoring, pneumococcal strain identification/assaying, environmental monitoring, critical sterility testing of raw materials, intermediates, Drug Substances, and Drug Products.	$24
Microbiology Tech 6	Microbiology Technician - Responsible for facilitating aseptic operations, water quality monitoring, pneumococcal strain identification/assaying, environmental monitoring, critical sterility testing of raw materials, intermediates, Drug Substances, and Drug Products.	$24

Benefits: Describe the components of the benefits (column R of the "Budget Details" sheet) included with the salary costs. For example: pension, health insurance, expatriate costs, etc.

PnuVax SL Bio only uses full-time employees (FTEs) to executed project work. PnuVax SL Bio provides a supplemental health benefits package that supplements the governmental health insurance program by providing for limited reimbursement for dental costs and various health related services otherwise not covered.

For clarity, all PnuVax SL Bio personnel who will work on the project listed in the above table are employed by PnuVax SL Bio on a full-time basis, not a part-time basis.

3. Travel

Provide rationale for the travel budgeted and assumptions used to determine appropriate number of trips and personnel required. Also include a brief rationale for how travel costs were estimated.

Four (4) destinations were listed in the travel budget for this project.

1. Montreal to Vancouver: Travel to Vancouver from Montreal is required for this project during the preclinical phase of this project. Before purchasing the custom finishing equipment required to prepare the clinical trial doses, PnuVax will visit the company for on-site demonstrations of the equipment and perform a quality audit. Three (3) technical personnel will attend, given the nature of the equipment and the importance of the step in which it is intended to be used. The trip is assumed to take 2 days, requiring 2 nights accommodation (3 rooms) and 2 days of per diems (3 persons) totaling 6 of each. One trip is assumed in Period 1, and one trip is assumed in Period 2. All flights will be standard economy (cheapest) class flights, and standard hotel rooms will be booked.

2. Montreal to Candler*:* Travel to Candler, North Carolina (Asheville) from Montreal is required for this project during all three phases of the project; i) preclinical, ii) phase 1 (adults safety), and iii) phase 2a (POC infants). Serological analyses are the critical indicator of PnuVax PCV-13 in the planned clinical trials during this project. As such, an in-person meeting is warranted upfront during the preclinical planning phase. A quality audit is also required for the serological work performed for the phase 1 adult trial and the phase 2a infant trial. To minimize travel costs, one (1) quality person will attend during the preclinical phase. The trip is assumed to take 2 days, requiring 2 nights accommodation (1 room) and 2 days of per diems (1 person) totaling 2 of each. One trip is assumed in Period 1. During the phase 1 project dimension, 2 personnel will be sent for auditing purposes in Period 2. The trip is assumed to take 2 days, requiring 2 nights accommodation (2 rooms) and 2 days of per diems (2 persons) totaling 4 of each. A comparable trip has been budgeted for in Period 2, to allow for a second audit during the phase 2a trial work. All flights will be standard economy (cheapest) class flights, and standard hotel rooms will be booked.

3. Montreal to Seattle*:* PnuVax has budgeted for travel from Montreal to Seattle in Periods 1, 2, and 3 of the proposed project. Trips to Seattle assume three (3) PnuVax personnel will travel from Montreal to Seattle, and that the trip will take 2 days requiring 2 nights accommodation (3 rooms) and 2 days of per diems (3 persons) totaling 6 of each. It is expected that in-person project updates may be valuable to the Foundation, and therefore one preclinical meeting, one phase 1 meeting, and one phase 2a meeting have been budgeted for during the course of this project between PnuVax and the Foundation. All flights will be standard economy flights, and standard hotels will be booked.

4. Montreal to Ottawa*:* Travel to Ottawa is required during this project to allow for PnuVax to meet with Health Canada during clinical trial application and approval proceedings, and also to meet with the clinical trial investigators at the Ottawa Hospital Research Institute (OHRI). Two tips to Ottawa have been budgeted for during the second Phase 1 Adult Clinical Trial dimension. Two trips to Ottawa have been also been budgeted for during the third Phase 2a Infant POC Clinical Trial dimension of this project. In all cases, three (3) personnel will travel to Ottawa, and each event is assumed to require 2 days requiring 2 nights accommodation (3 rooms) and 2 days of per diems (3 persons) totally 6 of each. One trip is planned for Period 1, two trips are planned for Period 2, and one trip is planned for Period 3.

Travel Cost Estimates: Travel costs were estimated based on current quoted travel costs from common online flight and accommodation providers, as well as on past actual travel expenditures. Travel costs will be reported as accrued, and may be lower if flights can be booked well in advance. During PnuVax's previous two grants with the Foundation, all travel costs were consistently within budgeted travel costs. It is highly unlikely the proposed travel budget will prove insufficient during project execution and we are confident that the travel cost estimates are realistic, if not somewhat conservative.

4. Consultants

Provide a brief description of the work to be performed by consultants in support of the overall project and describe any expenses that have been included.

N/A. No work is expected to be performed by consultants during this project, as PnuVax and PATH have arranged for PATH to be billed on a subcontractor basis as opposed to a consultant basis.

5. Capital Equipment

Provide a brief justification and description of any items required for the project with a unit cost of greater than $5,000 (U.S.$) and a useful life of more than one year.

Seven (7) pieces of equipment will be purchased for this project that are specifically required to prepare and characterize the clinical trial doses of PnuVax PCV-13 requisite to this project. The following equipment will be dedicated to PCV development activities, and is not of use to other projects.

1. Biosafety Level 2 Fermentor: This item will be used to help complete the first preclinical dimension of this project. This intermediate-scale unit will be purchased and used specifically to prepare pneumococcal polysaccharides for use in preparing the clinical trial doses. Monovalent conjugates will be prepared and formulated into test product using the polysaccharides yielded from this unit. This particular fermentor, together with its associated controls and probes, is required to accommodate the pathogenic nature of growing *Streptococcus pneumoniae* strains necessary to obtain cGMP polysaccharides for use in subsequent conjugation work.

2. Customized Flow Cytometer: This item will be used to help complete the first preclinical dimension of this project. A specialized gating system is required for OPA analyses, and PnuVax requires this unit in order to validate the OPA assay against traditional live OPK assays. Therefore, this will be a critical piece of equipment that will enable PnuVax to proceed with using the state of the art technique through which to evaluate antibody functionality (protective capacity) as opposed to antibody titers or concentrations. This piece of equipment together with the rate nephelometry equipment specific below is also critical in evaluating formulated vaccine potency, a required release assay for Health Canada licensure, WHO prequalification, and routine product release to market.

3. Protein Analyzer: This item will be used to help complete the first preclinical dimension of this project. This piece of equipment is required to allow for state of the art characterization of our carrier protein structure and molecular weight. It will allow for rapid and accurate CRM protein characterization otherwise not achievable. As a result, this piece of equipment is expected to become a workhorse for the PCV program. At a later time, beyond the timeframe of this project, it is likely that additional units similar to this piece of equipment may be required to keep up with the number of samples that must be tested and released in order to prepare all 13 conjugates.

4. HPLC: This item will be used to help complete the first preclinical dimension of this project. PnuVax requires an additional HPLC unit with a highly customized column and set of detectors that will allow for monovalent pneumococcal conjugate analyses, beyond the standard detection capabilities of the HPLC units that PnuVax already has on site. This new unit will be purchased to allow for rapid and enhanced accuracy of conjugate characterization, together with potency assay validation activities required during the preclinical phase of this project.

5. Rate Nephelometry Unit: This item will be used to help complete the first preclinical dimension of this project. This piece of equipment will be purchased as soon as funding is available, to allow for PnuVax to begin developing and validating its potency assay. An immunofluorescence unit will be used to perform standard rate nephelometry on formulated vaccine to detect for each of the 13 different conjugates in the formulated vaccine. Results will be validated against multiplexed immunoassaying developed during previous work as a bridging study to allow for multiple methods to be used to immunologically detect the different conjugates in a given formulated lot of test product.

6. Clinical Lot Finishing Unit: This item will be used to help complete the first preclinical dimension of this project, to help reduce high costs of outsourcing filling activities. This will allow for the multi-dose vial formats to be filled in-house to reduce overall filling costs, while the single-dose presentations are filled by an established filling subcontractor as per Health Canada requirements. It is expected that the filling unit purchased during this project can also later be used to accommodate the needs of the follow-up phase 2b infant pivotal registration trial and any additional WHO PQ-related trials that may be required to accommodate different dosing schedules mandated by the WHO.

7. Large-Scale Conjugation Unit: This item will be used to help complete the first preclinical dimension of this project. This piece of equipment is required to move from the current conjugation input scale of 1-10mg up to 100mg, to 100 mg -10g input scales. This is a readily commercially available unit that PnuVax has already identified and sized, and is ready to purchase once funding is available. Tests performed by the manufacturer confirm this unit will function as specified. This unit will become a workhorse for preparing our monovalent conjugates. Beyond the scope of this project, additional identical units could be purchased at a later time to increase throughput.

8. 400 MHz NMR Spectrometer: This item will be used to characterize APIs and in-process, intermediate, and drug substance samples generated over the course of vaccine preparation. APIs include purified polysaccharides and carrier protein, intermediates include activated polysaccharides, and drug substances denote monovalent bulk conjugates for the serotypes included in PnuVax PCV-13. Characterization via NMR during preclinical product development work is critical. Therefore, the purchase of this piece of equipment has been budgeted for in Period 1 of the project to allow for its use throughout the entire project.

Overall, these pieces of equipment will directly enhance polysaccharide and carrier protein preparation, fill our current conjugation scale-up equipment gap, and allow for development of the required remaining characterization activities largely related to conjugate release and formulated vaccine testing, including potency, and also related to long-term stability testing.

Quotes and all vendor details have now been arranged. The equipment is ready to be purchased as soon as funding is available, with the exception of the NMR spectrometer, which will slightly require longer lead-time for unit selection and installation. All pieces of equipment are required during the preclinical phase to allow for the preparation and characterization of the clinical doses of PnuVax PCV-13.

6. Other Direct Costs

Provide a brief description and rationale for other direct costs required, including cost assumptions used to develop the budget for these costs.

The “Other Direct Costs” for the project are only for supplies, including reagents and consumables specific to the project dimensions. An overview of the supplies needed for each dimension is as follows, and a detailed breakdown of the needed supplies for each outcome is provided in the budget spreadsheet.

1. Preclinical: During preclinical work for this project, polysaccharide and carrier protein must be prepared for conjugation and fully characterized using validated methods. Monovalent conjugates need to be prepared for all 13 serotypes included in the vaccine, and fully characterized, before formulating clinical trial lots of PnuVax PCV-13. Significant supplies are required to achieve the outcomes related to this dimension, with stringent quality standards and traceability required for the supplies used. The main supplies required for this dimension include GMP pneumococcal polysaccharides, GMP carrier protein, GMP excipients and adjuvant, purification and processing supplies, and assay reagents that must all be purchased on an ongoing basis to yield monovalent Drug Substances and formulated Drug Product. Formulation must be performed under strict aseptic conditions subject to environmental monitoring and under cGMP conditions appropriate for clinical material manufacturing, including specialty final containers and container manipulators. Additional supplies needed to prepare formulated vaccine and to perform filling and finishing include plastic laboratory consumables and sterile particle-free gowning supplies, and various types of tubing and labeling required for processing and release. Assay reagents range broadly based on the many compendial tests required for pneumococcal conjugate vaccines, however PnuVax has purchased these reagents for previous work and has reliable suppliers available for all reagents, including pneumococcal antisera. Shipping supplies are also required to send representative doses from the clinical trial lots to subcontractors for them to perform independent assaying and confirmatory animal studies as prerequisites to initiating the clinical studies.

2. Phase 1 (Adults): Batches of PnuVax PCV-13 clinical trial doses for the Phase 1 clinical trial in adults must be fully characterized both in-house and by independent contractors, and put on accelerated and long-term stability testing programs, and put through additional confirmatory animal studies depending on Health Canada requirements. Supplies related to this dimension are largely related to the characterization supplies including specialty reagents and plastic consumables that are needed to perform the mandatory tests laid out by US and EU compendia together with WHO recommendations and the WHO target product profile for PCVs. Specialty shipping supplies are required to send representative doses from the clinical trial lots to subcontractors that will perform independent dose characterization and additional animal studies if required by Health Canada. Customized supplies including immunological reagents and plastic consumables are also required to perform serological analyses of the human sera samples collected from the adults in the Phase 1 study performed as part of this dimension. Anticipated supplies vary as detailed in the budget, and include immunological antisera, specialty antibodies, immune cell lines, racked pipette tips, and sterile consumables such as serological pipettes.

3. Phase 2 (POC Infants): Batches of PnuVax PCV-13 clinical trial doses for the Phase 2a POC clinical trial in infants must be fully characterized both in-house and by independent contractors, and put on accelerated and long-term stability testing programs, and put through additional confirmatory animal studies depending on Health Canada requirements. Shipping supplies are required to send representative doses from the clinical trial lots to subcontractors that will perform independent dose characterization and additional animal studies if required by Health Canada. Customized supplies including immunological reagents and plastic consumables are also required to perform serological analyses of the human sera samples collected from the infants in the Phase 2a POC study performed as part of this dimension. Similarly to the phase 1 serological analyses supplies, items vary but include immunological antisera, specialty antibodies, immune cell lines, racked pipette tips, and sterile consumables such as serological pipettes.

Risks and Cost Assumptions: PnuVax now has the advantage of having already performed the manufacturing steps and most of the required PCV assays during previous work related to PnuVax PCV-13 product development. As a result, the risk of the proposed budget changing significantly for the listed required supplies is extremely low. To estimate costs for the proposed work, PnuVax has used actual costs from previous work (incorporating inflation) as estimates for the cost and quantity of supplies required for this proposed project. Budgeted amounts are in USD. However, it is notable that Canadian suppliers source almost all of their materials from the United

States. This means that as the value of the Canadian dollar changes with respect to USD, as do the costs realized by PnuVax for supplies. In the past, changes to the Canadian dollar value have resulted in a corresponding change to Canadian prices for materials. For our previous grants, this means that foreign exchange rate fluctuations have had very minimal impact on the actual realized costs versus the budgeted costs of supplies. Most costs will therefore remain within budget. The main uncertainty related to the supplies budget corresponds to the budgeted supplies needed to characterize the human sera collected from the clinical trials. It is possible that the cost for these supplies may vary slightly depending on Health Canada's requirements for the number of participants in each study. However, PnuVax has used best estimates for the number of participants in each study and is confident that the budgeted amounts for these materials are reasonable and realistic.

7. Sub-awards

List all sub-grantees or sub-contractors involved in this investment. Add more rows as needed.

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

If separate budgets are required (see above), please also submit a separate budget template and narrative for each sub-award.

Describe the work each organization is going to perform as well as the rationale for each organization chosen to participate on this project as a sub-grantee or sub-contractor. If organizations are TBD, include the assumptions used to estimate cost for the sub-award and the process and timeline you will be using to select these organizations.

Note: You will be required to submit the sub-award budget once final.

All sub-awards will be given on a sub-contract basis only, and the grantee remains solely PnuVax Incorporated.

No sub-grantees are affiliated with this project.

Budgeted costs are based on previous costs as models, or on quotes obtained for new work planned for this project.

Primary Sub-Contractor:

PnuVax SL Biopharmaceuticals: This subcontractor was used successfully during grants 1 and 2 in compliance with US tax law, and PnuVax Inc. will use PnuVax SL Bio as a sub-contractor in an identical manner during the proposed upcoming grant. Work will be performed by PnuVax SL Bio on a sub-contract basis, alongside relevant other sub-contractors in which case PnuVax SL Bio will serve as a pass-through to the multiple listed individual sub-contractors below (e.g. NeoPharm, etc.). PnuVax Inc. is the grantee, and will use FTEs and equipment available through PnuVax SL Bio to perform work on a sub-contract basis.

PnuVax Inc. plans to provide a $29,423,549 USD sub-award to PnuVax SL Biopharmaceuticals on a sub-contract basis. Work will be performed on a sub-contract basis only, alongside relevant other sub-contractors as needed. The detailed breakdown of this budget is included in a second Budget Template spreadsheet included with this grant application package.

The work of the additional sub-contracting organizations to be used by PnuVax SL Bio, and rationale for their selection, is as follows:

[redacted]

[1] [1] Vanderkooi OG, Scheifele DW, Girgenti D, Halperin SA, Patterson SD, Gruber WC, et al. Safety and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants and Toddlers Given With Routine Pediatric Vaccinations in Canada. The Pediatric Infectious Disease Journal. 2012;31:72-7.

8. Indirect Cost Rate

Briefly explain the indirect cost rate being charged on this project and the rationale and assumptions behind it.

PnuVax Inc. is the grantee and sole owner of PnuVax PCV-13 and all of its IP. PnuVax's sub-contractor PnuVax SL Bio has the Montreal cGMP manufacturing facility and FTEs required to execute the project.

The facility has operating costs that are linked to the ebb and flow of work on site. In the context of our PCV development program, facility use for PCV work is subject to the nature of the work being performed. PCV overheads related to facility use are allocated based on which subareas are used for PCV work, and in turn how frequently or to what extent these subareas are or will be used for PCV work.

Variable overheads are largely related to non-R&D FTEs and changes in utilities needs and use linked in real time to the activities being performed on site that are required to allow the facility to operate as needed and therefore for the project to occur. With respect to FTEs, PnuVax SL Bio is constantly evaluating and modifying its company size, increasing or decreasing the total number of FTEs as a function of project flow. For example, technician acquisition and turnover is performed on an ongoing basis to accommodate gaps and surges in project work. To date, this approach has been highly successful in allowing PnuVax SL Bio to minimize FTE-related overheads over time, and to resize the organization on an ongoing basis. Because of the significant work related to this proposed project, several new hires are already scheduled for 01JUL2017. This will ensure that PnuVax SL Bio is sized accordingly and has adequate personnel to execute the project.

The indirect costs PnuVax has budgeted for are largely facility-related, and include taxes and other general expenses that support the operation of PnuVax SL Bio.

For clarity, the following overhead categories have been classified as either Direct or Indirect Costs for the purposes of budgeting for OPP1172539:

Overhead Name	Overhead Type
Lease	Direct
Repairs & Maintenances	Direct
Utilities	Direct
Taxes	Indirect
Other (General Ops)	Indirect

During FY2013, PnuVax SL employed more employees than it did during subsequent FYs based on cash flow.

Similarly, more of the facility was in use and under routine operation during FY2013 as compared to subsequent fiscal years over which PnuVax SL operated in skeleton mode to keep previously unsupported operating costs as low as physically possible based on cash flow.

As a result, the operating costs reported on recent financial statements (FYs 2015, 2016) are not indicative of the operating costs that will be realized during the upcoming project. Areas of the facility that will be required to manufacture the clinical trial material must be turned on and maintained from hereon out to meet cGMPs appropriate to Product development.

The baseline costs from FY2013 Profit & Loss statement have therefore been used as baselines to in turn estimate the upcoming overheads to be realized during FYs 2017, 2018, and 2019.

The major Direct Cost overheads that will drive the direct facility costs realized during this project are:

Direct Facility Costs	2017	2018	2019
Lease	$297,552	$297,552	$297,552
Repairs & Maintenance	$560,000	$790,000	$810,000
Utilities	$1,065,000	$1,789,650	$2,331,000
Total	**$1,922,552**	**$2,877,202**	**$3,438,552**

The major Indirect Cost overheads that will drive the indirect facility costs realized during this project are:

Indirect Facility Costs	2017	2018	2019
Taxes	$581,450	$605,010	$612,149
Other (General Ops)	$1,660,000	$1,375,000	$925,000
Total	**$2,243,467**	**$1,982,028**	**$1,539,168**

Therefore, the overall major cost drivers for the overhead costs realized during this project are:

Overhead Category	Cost Category	2017	2018	2019
Lease	Direct Expense	$297,552	$297,552	$297,552
Repairs & Maintenances	Direct Expense	$560,000	$790,000	$810,000
Utilities	Direct Expense	$1,065,000	$1,789,650	$2,331,000
Taxes	Indirect Expense	$581,450	$605,010	$612,149
Other (General Ops)	Indirect Expense	$1,660,000	$1,375,000	$925,000
	Total	**$4,164,002**	**$4,857,212**	**$4,975,701**

The particularized breakdown of overhead expenses that comprise the Other Facility Overheads (General Ops) category are as follows (note that these only comprise the Other Operating Costs and do not include the costs related to the Facility Lease, Repairs & Maintenances, Utilities, or Taxes):

Expense	2013 P&L (CAN)	2013 P&L (USD)	2017 Budgeted (USD)	2018 Budgeted (USD)	2019 Budgeted (USD)
Accounting Expense	$686	$528	$11,538	$3,846	$3,846
Bank Fees	$6,019	$4,630	$4,921	$4,921	$4,921
Cleaning Expense	$66,106	$50,851	$216,176	$108,088	$72,059
Consulting Expense	$126,800	$97,539	$145,351	$145,351	$72,676
Depreciation	$88,896	$68,381	$68,381	$68,381	$68,381
Employee Meals	$10,413	$8,010	$40,050	$20,025	$10,013
Foreign Currency Gains and Losses	$13,479	$10,368	$27,549	$13,775	$6,887
Freight & Courier	$47,845	$36,804	$78,230	$39,115	$19,558
General Expenses	$126,014	$96,934	$103,022	$51,511	$51,511
Group Benefits Insurance Expense	$27,151	$20,886	$44,395	$44,395	$44,395
Information and Communication Technology	$14,309	$11,007	$23,396	$23,396	$23,396
Insurance Expense	$69,764	$53,665	$57,035	$57,035	$57,035
Interest Expense	$413	$317	$337	$337	$337
Legal fees	$3,491	$2,686	$34,615	$11,538	$11,538
Office Expenses	$25,216	$19,397	$41,229	$20,615	$20,615
Travels & Accommodations - International	$79,854	$61,426	$130,567	$130,567	$130,567
Travels & Accommodations - National	$12,276	$9,443	$20,072	$20,072	$20,072
Wages and Salaries (Non-R&D)	$240,858	$185,276	$590,733	$590,733	$295,366
Waste Disposal Expense	$17,146	$13,189	$28,035	$28,035	$14,017
Other Operating Expense	$976,736	$798,519	$1,665,634	$1,381,736	$927,190
Budgeted Other Operating Expenses	N/A	N/A	**$1,660,000**	**$1,375,000**	**$925,000**

2013 Baselines: The facility will be in greater use during 2017-2019 than it was during 2013, as a function of work performed.

2013 Other Operating Expenses PnuVax SL Bio	Historical Cost (CAN)	Historical Cost (USD)	Notes
Accounting Expense	$686	$528	*Did not include independent professional accounting services*
Bank Fees	$6,019	$4,630	*Representative*
Cleaning Expense	$66,106	$50,851	*Not representative of cleaning needs that will be required during Project*
Consulting Expense	$126,800	$97,539	*Additional consulting will be needed 2017-2019*
Depreciation	$88,896	$68,381	*Representative*
Employee Meals	$10,413	$8,010	*Will increase as function of increasing FTEs and work schedule*
Foreign Currency Gains and Losses	$13,479	$10,368	*Decrease in CAN dollar value will likely result in this being higher*
Freight & Courier	$47,845	$36,804	*Will increase or decrease depending on work flow*
General Expenses	$126,014	$96,934	*Will increase or decrease depending on work flow*
Group Benefits Insurance Expense	$27,151	$20,886	*Will increase as function of increasing FTEs*
Information and Communication Technology	$14,309	$11,007	*Will increase as function of increasing FTEs*
Insurance Expense	$69,764	$53,665	*Representative*
Interest Expense	$413	$317	*Representative*
Legal fees	$3,491	$2,686	*Will increase with company growth*
Office Expenses	$25,216	$19,397	*Will increase with company growth*
Travels & Accommodations - International	$79,854	$61,426	*Will increase with company growth*
Travels & Accommodations - National	$12,276	$9,443	*Will increase with company growth*
Wages and Salaries (Non-R&D)	$240,858	$185,276	*Will increase given upcoming increased administrative requirements*
Waste Disposal Expense	$17,146	$13,189	*Will increase as a function of increased facility use under cGMPs appropriate to the stage of development*
Other Operating Expenses	$976,736	$751,336	
Operating Expenses 2013	**$975,000**	**$750,000**	

2017 Budgeted Other Operating Costs Rationale:

2017 Projected Other Operating Expenses PnuVax SL Bio	Projected 2017 Cost (CAN)	Projected 2017 Cost (USD)	Notes
Accounting Expense	$15,000	$11,538	*Professional accounting services for audits etc.*
Bank Fees	$6,397	$4,921	*Assumed constant with 1.0628 inflation factor*
Cleaning Expense	$281,029	$216,176	*Assumed 4x, with 1.0628 inflation factor*
Consulting Expense	$188,957	$145,351	*Assumed 2x with 1.0628 inflation factor*
Depreciation	$88,896	$68,381	*Assumed constant*
Employee Meals	$52,066	$40,050	*Assumed 5x with 1.0628 inflation factor*
Foreign Currency Gains and Losses	$35,814	$27,549	*Assumed 2x, with 1.0628 inflation factor*
Freight & Courier	$101,699	$78,230	*Assumed 2x, with 1.0628 inflation factor*
General Expenses	$133,928	$103,022	*Assumed constant with 1.0628 inflation factor*
Group Benefits Insurance Expense	$57,713	$44,395	*Assumed 2x with 1.0628 inflation factor*
Information and Communication Technology	$30,415	$23,396	*Assumed 2x with 1.0628 inflation factor*
Insurance Expense	$74,146	$57,035	*Assumed constant with 1.0628 inflation factor*
Interest Expense	$439	$337	*Assumed constant with 1.0628 inflation factor*
Legal fees	$45,000	$34,615	*Growth and project activities will incur increased legal fees*
Office Expenses	$53,598	$41,229	*Anticipated to 2x with 1.0628 inflation factor*
Travels & Accommodations - International	$169,737	$130,567	*Assumed 2x with 1.0628 inflation factor*
Travels & Accommodations - National	$26,094	$20,072	*Assumed 2x with 1.0628 inflation factor*
Wages and Salaries (Non-R&D)	$767,953	$590,733	*Assumed 3x with 1.0628 inflation factor*
Waste Disposal Expense	$36,445	$28,035	*Assumed 2x with 1.0628 inflation factor*
Other Operating Expenses 2017	$2,165,324	$1,665,634	
Budgeted Other Operating Expenses 2017	N/A	**$1,660,000**	

2017:

- Increased accounting expenses will be incurred to obtain audited financial statements.
- Significant increases in cleaning requirements will occur to meet cGMP requirements appropriate to the stage of Product development.
- Highly intense work schedules and more employees on site will modestly increase realized meal costs.
- Increased orders of international materials related to the Project together with the decreased value of the CAN dollar as compared to the 2013 P&L will result in a modest increase in foreign current gains and losses.
- Increased shipments will occur during 2017.
- An increase in the number of employees will also increase the Group Benefits Insurance Expense.
- With growth and the paperwork anticipated for the upcoming project, a modest budget has been assumed for ongoing legal fees.
- Office expenses are assumed to approximately double, especially related to the administrative requirements related to maintaining cGMPs appropriate to the stage of Product development.
- Travel will increase by approximately two-fold based on planned domestic and international trips (e.g. Geneva, Gavi, WHO, etc.).
- Increased administrative requirements related to the project as well as to maintaining cGMPs appropriate to the stage of Product development will double salaries and wages for personnel unrelated to R&D activities.
- Based on the increase in the cleanliness standards related to cGMPs, waste pickup cost will approximately double.

2018 Budgeted Other Operating Costs Rationale:

2018 Projected Other Operating Expenses PnuVax SL Bio	Projected 2018 Cost (CAN)	Projected 2018 Cost (USD)	Notes
Accounting Expense	$5,000	$3,846	*Professional accounting services for audits etc.*
Bank Fees	$6,397	$4,921	*Assumed constant from 2017*
Cleaning Expense	$140,514	$108,088	*Assumed 0.5x 2017*
Consulting Expense	$188,957	$145,351	*Assumed 0.5x 2017*
Depreciation	$88,896	$68,381	*Assumed constant from 2017*
Employee Meals	$26,033	$20,025	*Assumed 0.5x 2017*
Foreign Currency Gains and Losses	$17,907	$13,775	*Assumed 0.5x 2017*
Freight & Courier	$50,850	$39,115	*Assumed 0.5x 2017*
General Expenses	$66,964	$51,511	*Assumed 0.5x 2017*
Group Benefits Insurance Expense	$57,713	$44,395	*Assumed constant from 2017*
Information and Communication Technology	$30,415	$23,396	*Assumed constant from 2017*
Insurance Expense	$74,146	$57,035	*Assumed constant from 2017*
Interest Expense	$439	$337	*Assumed constant from 2017*
Legal fees	$15,000	$11,538	*Moderate legal fees anticipated*
Office Expenses	$26,799	$20,615	*Assumed 0.5x 2017*
Travels & Accommodations - International	$169,737	$130,567	*Assumed constant from 2017*
Travels & Accommodations - National	$26,094	$20,072	*Assumed constant from 2017*
Wages and Salaries (Non-R&D)	$767,953	$590,733	*Assumed constant from 2017*
Waste Disposal Expense	$36,445	$28,035	*Assumed constant from 2017*
Other Operating Expenses 2018	$1,796,257	$1,381,736	
Budgeted Other Operating Expenses 2018	**$1,800,000**	**$1,375,000**	

2018:

- Accounting costs will be slightly lower than 2017, as most fiscal year statements will have been audited during 2017.
- Based on anticipated on-site activities and work flow, reductions in 2018 costs as compared to 2017 are expected to occur for cleaning costs, meal costs, foreign currency gains and losses, and general expenses.
- Office expenses will also be lower in 2018 as compared to 2017, based on the anticipated work schedule.

2019 Budgeted Other Operating Costs Rationale:

2019 Projected Other Operating Expenses PnuVax SL Bio	Projected 2019 Cost (CAN)	Projected 2019 Cost (USD)	Notes
Accounting Expense	$5,000	$3,846	*Assumed constant from 2018*
Bank Fees	$6,397	$4,921	*Assumed constant from 2018*
Cleaning Expense	$93,676	$72,059	*Assumed 0.33x 2017*
Consulting Expense	$94,478	$72,676	*Assumed 0.5x 2018*
Depreciation	$88,896	$68,381	*Assumed constant from 2018*
Employee Meals	$13,016	$10,013	*Assumed 0.5x 2018*
Foreign Currency Gains and Losses	$8,953	$6,887	*Assumed 0.5x 2018*
Freight & Courier	$25,425	$19,558	*Assumed 0.5x 2018*
General Expenses	$66,964	$51,511	*Assumed constant from 2018*
Group Benefits Insurance Expense	$57,713	$44,395	*Assumed constant from 2018*
Information and Communication Technology	$30,415	$23,396	*Assumed constant from 2018*
Insurance Expense	$74,146	$57,035	*Assumed constant from 2018*
Interest Expense	$439	$337	*Assumed constant from 2018*
Legal fees	$15,000	$11,538	*Assumed constant from 2018*
Office Expenses	$26,799	$20,615	*Assumed constant from 2018*
Travels & Accommodations - International	$169,737	$130,567	*Assumed constant from 2018*
Travels & Accommodations - National	$26,094	$20,072	*Assumed constant from 2018*
Wages and Salaries (Non-R&D)	$383,976	$295,366	*Assumed 0.5x 2018*
Waste Disposal Expense	$18,223	$14,017	*Assumed 0.5x 2018*
Other Operating Expenses 2019	$1,205,347	$927,190	
Budgeted Other Operating Expenses 2019	**$1,200,000**	**$925,000**	

2019:

- Based on the project flow, cleaning costs will be reduced in 2019 as compared to 2018, given that the project does not cover large-scale manufacturing and so the suite can at this time be cleaned on an as-needed basis as opposed to the rigid schedule that will be the case during 2017, as well as during 2018 to an extent.
- Consulting expenses are expected to decrease modestly during 2019.
- Based on work flow, reductions in cost are expected to occur for cleaning costs, meal costs, foreign currency gains and losses, and general expenses in 2019 as compared to 2018.
- Reductions in 2019 for non-R&D salaries and wages are expected in preparation for the gap between this project and the predicted next project.
- Waste disposal costs are also expected to decrease in 2019 as compared to 2018 based on work flow.

The allocation methodology assumes that:

Assumptions
The facility has a defined area available for use, totalling 100%.
The facility is defined into multiple subareas for use.
Overhead is allocated to each subarea based on the percentage area it comprises of the total facility area.
For each project, dedicated and shared areas may be required to complete the project. A dedicated area is defined as an area of the facility used solely for one project. A shared area is used for multiple projects.
Overhead for each dedicated project area is allocated entirely to that specific project.
Overhead for shared areas is divided among the different projects that use the space, proportionally to frequency and/or division of how the space is actually used. For example, if an area of the facility is used one third of the time for one project, then the overhead costs allocated to that project would be reported as 33% of the overhead costs related to that subarea.

Attribution of Facility Direct Costs to the Project

- Direct PCV-13 Attributable Facility Costs (2017): $314,417 USD
- Direct PCV-13 Attributable Facility Costs (2018): $1,129,301 USD
- Direct PCV-13 Attributable Facility Costs (2019): $1,349,632 USD

Comment [AB1]: Decreased as a result of new project start date of 01AUG2017 (Period 1 has 5 month duration now as opposed to 6 months)

Excluding "Other" Facility Subareas				2017		2018		2019	
Facility Subarea	Facility Subarea Allocation	PCV Subarea Usage	PCV - Facility Usage	PCV Project Duration	PCV Facilities Costs	PCV Project Duration	PCV Facilities Costs	PCV Project Duration	PCV Facilities Costs
Prokaryotic Suite	8%	100%	8.0%	0.42	64,085	1.0	230,176	1.0	275,084
Mammalian Suite	16%	0%	0.0%	0.42	-	1.0	-	1.0	-
Offices	5%	50%	2.5%	0.42	20,027	1.0	71,930	1.0	85,964
Research Laboratories	9%	75%	6.8%	0.42	54,072	1.0	194,211	1.0	232,102
Warehousing	44%	50%	22.0%	0.42	176,234	1.0	632,984	1.0	756,481
	82%		39.3%		$314,417		$1,129,302		$1,349,632

Source: PnuVax Facility Costs 13JUL2017.xlsx

Calculation of the Indirect Cost Rate Applied to Budget

- Based on the 01FEB2017 Indirect Cost Policy, the Indirect Cost Rate can be up to 15% for a For-Profit organization, and is calculated as follows:

Indirect Cost Rate = Budgeted Indirect Costs / Budgeted Total Direct Costs

Budgeted Indirect Costs attributable to PCV work: $2,387,569 USD
Budgeted Total Direct Costs attributable to PCV work: $27,035,980 USD

Therefore, the Indirect Cost Rate = $2,387,569 USD / $27,035,980 = 9%

Including "Other" Facility Subareas

Facility Subarea	Facility Subarea Allocation	PCV Subarea Usage	PCV - Facility Usage
Prokaryotic Suite	8%	100%	8.0%
Mammalian Suite	16%	0%	0.0%
Offices	5%	50%	2.5%
Research Laboratories	9%	75%	6.8%
Warehousing	44%	50%	22.0%
Other	18%	50%	9.0%
	100%		48.3%

	2017		2018		2019	
	PCV Project Duration	PCV Facilities Costs	PCV Project Duration	PCV Facilities Costs	PCV Project Duration	PCV Facilities Costs
Prokaryotic Suite	0.42	64,085	1.0	230,176	1.0	275,084
Mammalian Suite	0.42	-	1.0	-	1.0	-
Offices	0.42	20,027	1.0	71,930	1.0	85,964
Research Laboratories	0.42	54,072	1.0	194,211	1.0	232,102
Warehousing	0.42	176,234	1.0	632,984	1.0	756,481
Other	0.42	72,096	1.0	258,948	1.0	309,470
		$386,513		$1,388,250		$1,659,101

Indirect Costs Attributable to PCV

Indirect Cost Description	2017 PCV Project Duration	2017 PCV Indirect Costs	2018 PCV Project Duration	2018 PCV Indirect Costs	2019 PCV Project Duration	2019 PCV Indirect Costs
PCV Attributable "Other" Subarea Costs	0.42	72,096	1.0	258,948	1.0	309,470
Portion of Facility Taxes Attributable to PCV	0.42	95,091	1.0	237,466	1.0	240,268
Portion of Facility Other Operating Costs Attributable to PCV	0.42	271,479	1.0	539,688	1.0	363,063
		$438,666		$1,036,102		$912,801

Indirect Cost Rate Calculation

Budgeted Direct Costs w/o Direct PCV Attributable Facility Costs	$24,242,629
Direct Facility Attributable Costs	$2,793,351
Budgeted Direct Costs w/ Direct Facility Attributable Costs	$27,035,980
Budgeted Indirect Costs Attributable to PCV	$2,387,569
Indirect Cost Rate	**9%**

Source: PnuVax Facility Costs 13JUL2017.xlsx

Overhead costs unrelated to the PCV program or not covered by the PnuVax grant are the responsibility of PnuVax SL Bio, and are covered via CMO project funds and/or Canadian government assistance. PnuVax SL Bio does not foresee any issues in continuing to cover its other overheads unrelated to their PCV program using these approaches.

9. Currency Exchange

Briefly describe any foreign currency exchange exposure with this investment. Which costs included in the budget are exposed to exchange risk? How much do these costs total?

As with our previous grants, this grant will be exchanged from US dollars to Canadian dollars, as PnuVax Inc. is a Canadian corporation, as is its subcontractor PnuVax SL Bio. This project will be largely executed in Canada, with the exception of limited international sub-contracted work. Therefore, actual costs will be mostly realized in Canadian dollars, and all funds used to pay invoices will be Canadian. Actual costs will in turn be converted to USD based on the realized exchange rates for Foundation reporting purposes.

There is always the risk that if the exchange rate changes significantly during the project, PnuVax may need to request additional funding. However, this is a very low risk and is also unlikely, as this would require a significant gain in the Canadian dollar value over the course of this project that is improbable based on current market predictions.

During previous grants with the Foundation, best judgment was used to select a foreign exchange rate upfront based on Canadian dollar trends. This has worked well during the past two grants, and so PnuVax and the Foundation have once again selected an exchange rate together for the proposed project, in this case 1.30, based on the current USD to CAN conversion rates.

As a result, PnuVax does not perceive any significant concerns related to current exchange for the upcoming project. Currency gains realized during previous projects were effectively used to allow for additional FTE labor on the projects, which greatly ameliorated outcomes given the inherent difficulty in predicting labor requirements for any project. Currency gains (if any) realized during this project will only be used toward project-specific activities to ameliorate and/or expedite completion of this project.

In terms of costs included in the budget that will be exposed to the USD to CAN exchange, 100% of the funds will be transferred to Canadian dollars and used to execute the project. Most of the proposed grant will be spent within Canada, and the remaining budgeted funds used to pay for subcontracted services and/or materials obtained from the US or internationally.

10. Other Sources of Support for this Project

If you are requesting funding from the foundation for only a portion of this project and will depend on funds from other sources, please describe your contingency plans if full project funding does not become available. If you have applied for funding from other sources which overlap with the funding requested in this proposal, please indicate the nature and timing of that potential funding. Any expected in-kind contributions (e.g. drug donations, personnel time) should be included in the description.

NOTE: Names of the other sources and their expected dollar (U.S.$) contributions should be included on the 'Financial Summary & Reporting' sheet of the budget in the Funding Plan table.

N/A. There are no other sources of funding for the proposed PCV project.

11. Other

Please feel free to use this section to provide any other commentary or information that helps to describe and justify the budget request presented. This may include assumptions and rationale behind indirect costs, risks, anomalies or other assumptions foundation staff should be aware of when reviewing the budget.

N/A. PnuVax is confident that the budget is realistic given the significant scope of this project, and does not foresee budget drift. While it is always possible that clinical materials could take longer to prepare and release, or that clinical studies could take longer than anticipated to be completed and evaluated, any of these realized shifts or delays in the overall schedule that may occur are not expected to change the overall project cost and would only impact the overall project timeline. PnuVax is sensitive to the desperate need for a low-cost PCV, and so will endeavor to complete all milestones as quickly as physically possible.

Privacy and Non-Confidentiality Notice

The foundation is required by the IRS to publish a list of its grants. We may also provide a general description of our grants and contracts on our web sites, in press releases, and in other marketing materials. Subject to the foundation's Privacy Policy, the foundation may also share information you provide to us (either orally or in writing) with third parties, including external reviewers, key partners and co-funders. This document is subject to the foundation's Terms of Use.

This page provides a quick overview of the BMGF budget template to orient you before getting started.
As you populate the sheets, you will find direct links to specific instructions with examples throughout the template.
The full instruction document can be accessed here.
Frequently Asked Questions (FAQs) can be accessed here.

Grantee Input Sheets
These first three sheets need to be filled out by the grantee for every grant.

Optional: Grantees can comment on the auto-generated preliminary payment schedule here.

General Information	→	Budget Details	→	Financial Summary & Reporting	→	Payment & Reporting Schedule
*Enter the required basic information into this sheet **before** populating any of the other sheets.*		*For each of the 6 expense categories, enter the items that collectively make up the grant budget into this sheet.*		*Review the summary tables from the Budget Detail sheet and add further information (where applicable). This sheet is also used to enter actuals expenditures and projections as part of reporting.*		*This sheet is used by the grantee to review an auto-generated preliminary payment schedule and by BMGF to make any changes before incorporating it into the grant agreement.*

Important information for working with the template

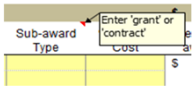
Legend for cell formatting

Input **cells are colored** according to the following scheme. At the time of budgeting, populate only light yellow cells.

Enter information into light yellow cells
Enter actual expenditures into green cells
Blue cells will be populated by BMGF

Hints for specific data entry fields

For some fields, a **red triangle in the upper right corner** indicates that a hint is available when hovering the mouse over the cell.



Error checking

For some cells, an automatic error check will show its **value in red** if it appears to be populated incorrectly or if the calculation yields a result that is inconsistent with another value.

incorrect entry
01-Jan-15

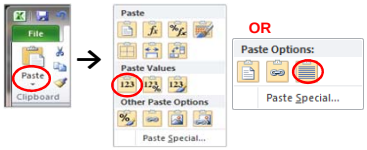
Inconsistent result
$ 124,237

Cash vs. Projected Actuals (Accruals)

All **actual** amounts reported should be based on ***cash spent***, not PROJECTED (or ACCRUED) for the remainder of the period.

Copying data into the template

Use ***Paste Values*** whenever transferring data from an external source into the template. If not, the template can become corrupted



*In addition to the three sheets described above, there are **several additional sheets** included in the template, some of them optional and/or hidden. Grantees **do not need to use** these additional sheets, but for transparency, you will find an overview below.*

*If you would like to include additional information (or are asked for it by BMGF) in this file, it is **OK to add extra sheets** for this purpose. However, please **do not make any changes to the structure, formatting or formulas of the existing sheets.***

BMGF Work Sheets
These three sheets are primarily used by BMGF to analyze and manage the grant. Grantees can provide input in the Payment & Reporting Schedule sheet. You may use them yourself, but please do not enter or alter any data or formulas

Payment & Reporting Schedule	Analytics	Budget Pivot (typically hidden)
This sheet is used by the grantee to review an auto-generated preliminary payment schedule and by BMGF to make any changes before incorporating it into the grant agreement.	*Contains two analytic features: a set of Basic Charts and a Comparison Tool*	*Excel Pivot table that can be used to analyze the data in the Budget Detail sheet.*

Historic or Background Information
These sheets are used by BMGF to preserve historic information throughout the grant or for administrative purposes. Please do not make any changes to these sheets.

[Historic Budget Details] 0, 1 or more sheets (typically hidden)	Historic Budget Summaries (typically hidden)	Config (typically hidden)
If a grant budget revision takes place, the previous version of the Budget Detail sheet can be preserved as a separate sheet for reference.	*If grant budget revisions take place, this sheet can be used to preserve previous versions of the Budget Summary for reference.*	*Used for administrative purposes to populate dropdown lists etc. throughout the template.*

PnuVax Incorporated
PnuVax PCV-13 Development Through POC in Infants

BILL & MELINDA GATES foundation

Prepared by: Donald F. Gerson

Date submitted: 13-Jul-17

Template version 2017-02-01

Legend for cell formatting:
Enter information into light yellow cells
Enter actual expenditures into green cells
Blue cells will be populated by BMGF

GENERAL INFORMATION

Go to instructions for this page…

Proposal Information

Organization Name	PnuVax Incorporated
Proposal Title	PnuVax PCV-13 Development Through POC in Infants
Opportunity ID	OPP1172539
Is this a Sub-Award Budget?	No
Requested Amount	**$29,423,549**
Total Project Cost	**$29,423,549**

Budgeting & Reporting Periods

Anticipated Start Date	01-Aug-17
Anticipated End Date	31-Dec-19
Project Duration (months)	29

Please ensure that you are selecting the correct reporting cadence before inputting the budget details. If you need to readjust the reporting periods, the budget details will need to be revised as well to reflect the date changes.
Note that if your grant is an Expenditure Responsibility (ER) grant, you must select "**Align with fiscal year**" as the reporting cadence.

Preferred Reporting Cadence Align with fiscal year **Next FY begins on** 01-Jan-18

Reporting Periods	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10
Period Start Date	**01-Aug-17**	**01-Jan-18**	**01-Jan-19**							
Period End Date	**31-Dec-17**	**31-Dec-18**	**31-Dec-19**							
Number of Months	5.0	12.0	12.0							

Indirect Cost Rate(s)

Please enter indirect cost rates in accordance with the indirect cost policy:
Read BMGF Indirect Cost policy…

Organization Type For-profit organization

Indirect Cost Rate on Primary Grantee's Portion	0%	*Maximum rates for selected organization type are*
Primary Grantee's Indirect Cost Rate on Sub-award Portion	9%	*15%.*

Other Budget Factors

More info…	**Will funds be spent in non-USD currencies?**	Yes — *Please complete the table at the bottom of the Financial Summary & Reporting Tab*
More info…	**Will the budget be broken down by an additional dimension?** (e.g. outcomes/outputs, project components/phases)	No
More info…	**Will the total cost of this project require contributions of funding from sources other than BMGF?** (e.g. either by your organization or others)	No
More info…	**Is this a new version of a previously approved budget?** (e.g. supplement)	No

BUDGET DETAILS

Go to instructions for this page…

Enter budget details for each expenditure category below.

	Additional Dimension	Description	Purpose	Unit Cost	Period 1 Aug-17 - Dec-17 Quantity	Period 2 Jan-18 - Dec-18 Quantity	Period 3 Jan-19 - Dec-19 Quantity	Period 4 - Quantity	Period 5 - Quantity	Addtl. Info	Addtl. Info	Period 1 Aug-17 - Dec-17 Amount	Period 2 Jan-18 - Dec-18 Amount	Period 3 Jan-19 - Dec-19 Amount	Period 4 - Amount	Period 5 - Amount	TOTAL AMOUNT	TOTAL UNITS	% of Total Direct Cost
Personnel					-	-	-	-	-			$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
	Additional Dimension	Name	Job Title	Annual Salary per FTE	Period 1 FTE Allocation	Period 2 FTE Allocation	Period 3 FTE Allocation	Period 4 FTE Allocation	Period 5 FTE Allocation	% Inflation (Annualized)	% Benefits	Period 1 Personnel Cost	Period 2 Personnel Cost	Period 3 Personnel Cost	Period 4 Personnel Cost	Period 5 Personnel Cost	Total Personnel Cost	Total FTE Allocation	% of Total Direct Cost
1												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
← *Unhide additional rows if needed*																			
Travel												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
	Additional Dimension	Travel Cost Item Description	Purpose of Trip	Cost per Item	Period 1 No. of Items	Period 2 No. of Items	Period 3 No. of Items	Period 4 No. of Items	Period 5 No. of Items	N/A	N/A	Period 1 Travel Cost	Period 2 Travel Cost	Period 3 Travel Cost	Period 4 Travel Cost	Period 5 Travel Cost	Total Travel Cost	Total Number of Units	% of Total Direct Cost
1												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
← *Unhide additional rows if needed*																			
Consultants												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
	Additional Dimension	Consultant Name	Role / Purpose of Engagement	Billing Rate / Project Cost	Period 1 Billable Units	Period 2 Billable Units	Period 3 Billable Units	Period 4 Billable Units	Period 5 Billable Units	Billing Unit / Expense	N/A	Period 1 Consultants Cost	Period 2 Consultants Cost	Period 3 Consultants Cost	Period 4 Consultants Cost	Period 5 Consultants Cost	Total Consultants Cost	Total Number of Units	% of Total Direct Cost
1												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
← *Unhide additional rows if needed*																			
Capital Equipment												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
	Additional Dimension	Equipment Description	Purpose of Equipment	Cost per Item	Period 1 Quantity	Period 2 Quantity	Period 3 Quantity	Period 4 Quantity	Period 5 Quantity	N/A	N/A	Period 1 Equipment Cost	Period 2 Equipment Cost	Period 3 Equipment Cost	Period 4 Equipment Cost	Period 5 Equipment Cost	Total Equipment Cost	Total Number of Units	% of Total Direct Cost
1												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
← *Unhide additional rows if needed*																			
Other Direct Costs												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
	Additional Dimension	Item description	Purpose of Item	Cost per Item	Period 1 Quantity	Period 2 Quantity	Period 3 Quantity	Period 4 Quantity	Period 5 Quantity	N/A	N/A	Period 1 Other Direct Cost	Period 2 Other Direct Cost	Period 3 Other Direct Cost	Period 4 Other Direct Cost	Period 5 Other Direct Cost	Total Other Direct Cost	Total Number of Units	% of Total Direct Cost
1												$ -	$ -	$ -	$ -	$ -	$ -	-	0.0%
← *Unhide additional rows if needed*																			
Sub-awards												$ 5,448,834	$ 10,999,815	$ 10,587,331	$ -	$ -	$ 27,035,980	27,035,980	100.0%
	Additional Dimension	Sub-award Organization	Scope of Sub-award	N/A	Period 1 Amount	Period 2 Amount	Period 3 Amount	Period 4 Amount	Period 5 Amount	Sub-award Type	% Indirect Cost	Period 1 Sub-award Cost	Period 2 Sub-award Cost	Period 3 Sub-award Cost	Period 4 Sub-award Cost	Period 5 Sub-award Cost	Total Sub-award Cost	Total Number of Units	% of Total Direct Cost
1		PnuVax SL Biopharmaceuticals, Inc.	Sub-contract to PnuVax SL Bio		$ 5,448,834	$ 10,999,815	$ 10,587,331	$ -	$ -	Contract	10%	$ 5,448,834	$ 10,999,815	$ 10,587,331	$ -	$ -	$ 27,035,980		100.0%
← *Unhide additional rows if needed*																			

FINANCIAL SUMMARY & REPORTING

Expand/Collapse sections to see/hide the budget and actuals & projections→

Budget

Budget

Prepared by: Donald F. Gerson

Go to **budgeting** instructions for this page…

Go to **reporting** instructions for this page…

	Period 1	Period 2	Period 3	Period 4	Period 5	
	Aug-17 - Dec-17	Jan-18 - Dec-18	Jan-19 - Dec-19	-	-	
	Budget	Budget	Budget	Budget	Budget	

Cash Flow Summary (BMGF Funds Only)

NOTE: Blue cells will be populated by BMGF after budget has been reviewed.

Revenue						TOTAL
BMGF Payment(s)						$ -
Interest Earned	-	-	-	-	-	-
Other Gains / (Losses)	-	-	-	-	-	-
Carry-over Amount from Prior Period	-	(5,930,025)	(17,901,242)	(29,423,549)	(29,423,549)	N/A
TOTAL CASH AVAILABLE BY PERIOD	**-**	**(5,930,025)**	**(17,901,242)**	**(29,423,549)**	**(29,423,549)**	**N/A**
Expenditure						
BMGF Funds Spent on Direct Cost	5,448,834	10,999,815	10,587,331	-	-	27,035,980
BMGF Funds Spent on Indirect Cost	481,191	971,402	934,976	-	-	2,387,569
Interest Spent	-	-	-	-	-	-
TOTAL EXPENDITURE BY PERIOD	**5,930,025**	**11,971,218**	**11,522,307**	**-**	**-**	**29,423,549**
BALANCE AT PERIOD END	**$ (5,930,025)**	**$ (17,901,242)**	**$ (29,423,549)**	**$ (29,423,549)**	**$ (29,423,549)**	**N/A**

Summary by Expense Category

Category						TOTAL	*% of Total Direct Cost*
Personnel	$ -	$ -	$ -	$ -	$ -	$ -	*0%*
Travel	-	-	-	-	-	-	*0%*
Consultants	-	-	-	-	-	-	*0%*
Capital Equipment	-	-	-	-	-	-	*0%*
Other Direct Costs	-	-	-	-	-	-	*0%*
Sub-awards	5,448,834	10,999,815	10,587,331	-	-	27,035,980	*100%*
TOTAL DIRECT COST	**5,448,834**	**10,999,815**	**10,587,331**	**-**	**-**	**27,035,980**	***100%***
Indirect Cost	481,191	971,402	934,976	-	-	2,387,569	*9%*
TOTAL BUDGET	**$ 5,930,025**	**$ 11,971,218**	**$ 11,522,307**	**$ -**	**$ -**	**$ 29,423,549**	***109%***

Breakdown along Additional Dimension

						TOTAL	*% of Total Direct Cost*
Preclinical	$ -	$ -	$ -	$ -	$ -	$ -	
Phase 1	-	-	-	-	-	-	
Phase 2	-	-	-	-	-	-	
N/A	-	-	-	-	-	-	
N/A	-	-	-	-	-	-	
TOTAL DIRECT COST	-	-	-	-	-	-	

Total Project Cost

Category						TOTAL	*% of Total*
Personnel						$ -	*0%*
Travel						-	*0%*
Consultants						-	*0%*
Capital Equipment						-	*0%*
Other Direct Costs						-	*0%*
Sub-awards						-	*0%*
Indirect Costs						-	*0%*
TOTAL PROJECT COST	$ 5,930,025	$ 11,971,218	$ 11,522,307	$ -	$ -	29,423,549	***100%***

Funding Plan

Sources of Funding						TOTAL	*% of Total*
BMGF - Direct Cost	$ 5,448,834	$ 10,999,815	$ 10,587,331	$ -	$ -	$ 27,035,980	*92%*
BMGF - Indirect Cost	481,191	971,402	934,976	-	-	2,387,569	*8%*
1						-	*0%*
2						-	*0%*
3						-	*0%*
4						-	*0%*
5						-	*0%*
TOTAL FUNDING PLAN	5,930,025	11,971,218	11,522,307	-	-	29,423,549	***100%***
Total BMGF and Secured Funding						-	*0%*
Total Potential Funding	5,930,025	11,971,218	11,522,307	-	-	29,423,549	*100%*
OVER/(UNDER) FUNDING	$ -	$ -	$ -	$ -	$ -	$ -	*0%*
Cumulative overage / (underage)	-	-	-	-	-	-	

Exchange Rates

	Enter Currency Symbol (e.g. INR, GBP, ...)	FX Rate (Units/USD)
1	CAD	1.30
2		
3		
4		
5		
6		
7		
8		
9		
10		

PAYMENT SCHEDULE

Go to instructions for this page…

This sheet is intended for grantee review. Please use the comment box to provide input and do not edit any other information.

The calculator below automatically generates a payment schedule based your inputs in other sheets. Please review the table at the bottom of the page and provide your comments on the proposed schedule.
Please note that BMGF may make changes to the schedule based on your inputs and other factors.

Grant Agreement

Please note that the table below is initially auto-populated and may be changed by BMGF as the payment & reporting schedule is finalized
In case of inconsistencies between the table below and the Grant Agreement, the Grant Agreement overrides the table below.

Investment Period	Target, Milestone, or Reporting Deliverable	Due By	Payment Date	Payment Amount (U.S.$)
			Within 15 days upon receipt of Counter-signed Grant Agreement	$8,857,053.12
August 1, 2017 to December 31, 2017	Progress Report	January 31, 2018	March 2018	Up to $11,861,457
December 31, 2017 to December 31, 2018	Progress Report	January 31, 2019	March 2019	Up to $8,705,040
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Progress Report			
	Final Report			
			Total Grant Amount	**Up to $29,423,549**

Grantee Comments

[Please use this space to comment on the automatically generated payment & reporting schedule.]

ANALYTICS

Go to instructions for this page…

This sheet is primarily intended for BMGF use and does not require any grantee input.

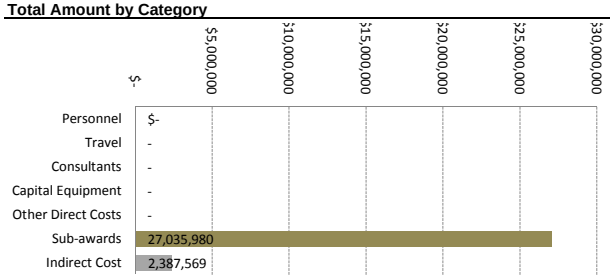
You may use the features to analyze the budget and actuals & projections, but please do not edit anything other than using the yellow drop-down boxes.
Available features include a set of Basic Graphs and a Comparison Tool (as the grant progresses).

Basic Graphs

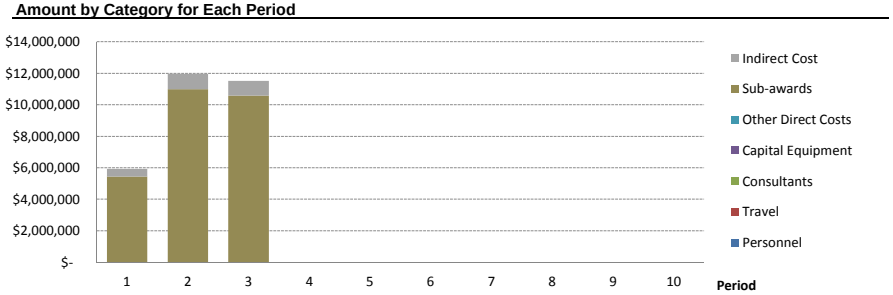
Figures to be used for charts Budget

Category	Period 1 Aug-17 - Dec-17 Budget	Period 2 Jan-18 - Dec-18 Budget	Period 3 Jan-19 - Dec-19 Budget	Period 4 - Budget	Period 5 - Budget	Period 6 - Budget	Period 7 - Budget	Period 8 - Budget	Period 9 - Budget	Period 10 - Budget	TOTAL	% of Direct Cost
Personnel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	0%
Travel	-	-	-	-	-	-	-	-	-	-	-	0%
Consultants	-	-	-	-	-	-	-	-	-	-	-	0%
Capital Equipment	-	-	-	-	-	-	-	-	-	-	-	0%
Other Direct Costs	-	-	-	-	-	-	-	-	-	-	-	0%
Sub-awards	5,448,834	10,999,815	10,587,331	-	-	-	-	-	-	-	27,035,980	100%
TOTAL DIRECT COST	**5,448,834**	**10,999,815**	**10,587,331**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**27,035,980**	**100%**
Indirect Cost	481,191	971,402	934,976	-	-	-	-	-	-	-	2,387,569	9%
TOTAL	**$ 5,930,025**	**$ 11,971,218**	**$ 11,522,307**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 29,423,549**	**109%**

Total Amount by Category

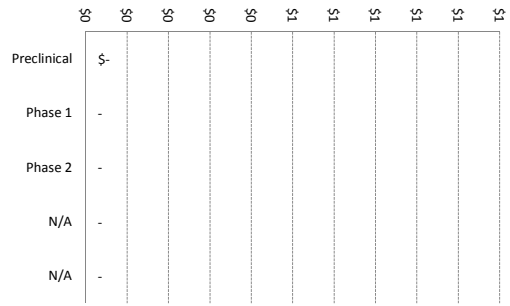


Amount by Category for Each Period

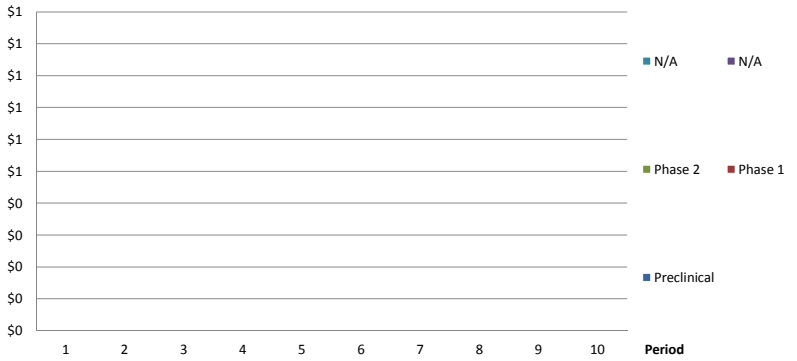


Additional Dimension	Period 1 Aug-17 - Dec-17 Budget	Period 2 Jan-18 - Dec-18 Budget	Period 3 Jan-19 - Dec-19 Budget	Period 4 - Budget	Period 5 - Budget	Period 6 - Budget	Period 7 - Budget	Period 8 - Budget	Period 9 - Budget	Period 10 - Budget	TOTAL
Preclinical	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Phase 1	-	-	-	-	-	-	-	-	-	-	-
Phase 2	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-
TOTAL DIRECT COST	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Total Amounts for Additional Dimension



Amounts for Additional Dimension



Comparison Tool

Figures to be used for baseline: Budget

Figures to be used for comparison: End of Period 1

Comparison by Expense Category

Baseline	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	TOTAL	Cumul. Actual
	Aug-17 - Dec-17	Jan-18 - Dec-18	Jan-19 - Dec-19	-	-	-	-	-	-	-		
Category	Budget	Budget	Budget	Budget	Budget	Budget	Budget	Budget	Budget	Budget		
Personnel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	-	-	-	-	-	-	-	-	-	-	-	-
Consultants	-	-	-	-	-	-	-	-	-	-	-	-
Capital Equipment	-	-	-	-	-	-	-	-	-	-	-	-
Other Direct Costs	-	-	-	-	-	-	-	-	-	-	-	-
Sub-awards	5,448,834	10,999,815	10,587,331	-	-	-	-	-	-	-	27,035,980	5,448,834
Indirect Cost	481,191	971,402	934,976	-	-	-	-	-	-	-	2,387,569	481,191
TOTAL	**$ 5,930,025**	**$ 11,971,218**	**$ 11,522,307**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 29,423,549**	**$ 5,930,025**

Comparison												
Category	Actual	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected		Cumul. Actual
Personnel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	-	-	-	-	-	-	-	-	-	-	-	-
Consultants	-	-	-	-	-	-	-	-	-	-	-	-
Capital Equipment	-	-	-	-	-	-	-	-	-	-	-	-
Other Direct Costs	-	-	-	-	-	-	-	-	-	-	-	-
Sub-awards	-	-	-	-	-	-	-	-	-	-	-	-
Indirect Cost	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Difference in $	*Latest Actual*											
Category	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	TOTAL	Cumul. Variance
Personnel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	-	-	-	-	-	-	-	-	-	-	-	-
Consultants	-	-	-	-	-	-	-	-	-	-	-	-
Capital Equipment	-	-	-	-	-	-	-	-	-	-	-	-
Other Direct Costs	-	-	-	-	-	-	-	-	-	-	-	-
Sub-awards	**(5,448,834)**	(10,999,815)	(10,587,331)	-	-	-	-	-	-	-	(27,035,980)	(5,448,834)
Indirect Cost	**(481,191)**	(971,402)	(934,976)	-	-	-	-	-	-	-	(2,387,569)	(481,191)
TOTAL	**$ (5,930,025)**	**$ (11,971,218)**	**$ (11,522,307)**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ (29,423,549)**	**$ (5,930,025)**

Difference in %	*Latest Actual*											
Category	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	TOTAL	Cumul. Variance
Personnel	-	-	-	-	-	-	-	-	-	-	-	-
Travel	-	-	-	-	-	-	-	-	-	-	-	-
Consultants	-	-	-	-	-	-	-	-	-	-	-	-
Capital Equipment	-	-	-	-	-	-	-	-	-	-	-	-
Other Direct Costs	-	-	-	-	-	-	-	-	-	-	-	-
Sub-awards	**-100%**	-100%	-100%	-	-	-	-	-	-	-	-100%	-100%
Indirect Cost	**-100%**	-100%	-100%	-	-	-	-	-	-	-	-100%	-100%
TOTAL	**-100%**	**-100%**	**-100%**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-100%**	**-100%**

Comparison for Additional Dimension

Baseline	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	TOTAL	Cumul. Actual
	Aug-17 - Dec-17	Jan-18 - Dec-18	Jan-19 - Dec-19	-	-	-	-	-	-	-		
	Budget	Budget	Budget	Budget	Budget	Budget	Budget	Budget	Budget	Budget		
Preclinical	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Phase 1	-	-	-	-	-	-	-	-	-	-	-	-
Phase 2	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL DIRECT COST	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Comparison	Actual	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected		Cumul. Actual
Preclinical	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Phase 1	-	-	-	-	-	-	-	-	-	-	-	-
Phase 2	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL DIRECT COST	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Difference in $	*Latest Actual*											
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	TOTAL	Cumul. Variance
Preclinical	**$ -**	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Phase 1	**-**	-	-	-	-	-	-	-	-	-	-	-
Phase 2	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
N/A	**-**	-	-	-	-	-	-	-	-	-	-	-
TOTAL DIRECT COST	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Difference in %	*Latest Actual*											
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	TOTAL	Cumul. Variance
Preclinical	-	-	-	-	-	-	-	-	-	-	-	-
Phase 1	-	-	-	-	-	-	-	-	-	-	-	-
Phase 2	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
N/A	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL DIRECT COST	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**

EXHIBIT 3

From: Trevor Mundel <Trevor.Mundel@gatesfoundation.org>
Sent: Wednesday, September 12, 2018 7:36 AM
To: [redacted]
Cc: lee@mullowney.com; Ruth Atherton; Keith Klugman
Subject: PnuVax Grant OPP1172539
Attachments: PnuVax Instructions for the Return of Funds.docx; OPP1172539_2018 _Pnuvax_Final_narrative.docx; OPP1172539_2018_PnuVax _Progress_Budget.xlsx; OPP1172539_2018_PnuVax_Progress_ IPDP (1).docx

Importance: High

Dear Dr. Gerson:

The Bill & Melinda Gates Foundation (the "Foundation") and PnuVax Incorporated ("PnuVax") entered into a Grant Agreement dated August 17, 2017 (the "Grant Agreement") regarding a grant to develop a 13-valent pneumococcal conjugate vaccine that is available to GAVI countries at an affordable price (the "Project"), as well as a Global Access Commitment Agreement dated August 17, 2017 (the "Global Access Agreement") specifying certain Global Access Commitments.

The purpose of this letter is to give notice that the Foundation hereby terminates the above-referenced Grant Agreement for material breach of and failure to comply with the terms of the Grant Agreement, including, without limitation, failure to comply with the restrictions on PnuVax's use of grant funds received from the Foundation, failure to keep adequate records, failure to maintain segregation of grant funds, using grant funds to reimburse expenses incurred prior to the start date of the Grant Agreement, failure to meet certain milestones, and failure to use the income earned on the grant funds for the Project.

In conjunction with this termination, we hereby advise you of the following:

- PnuVax should provide a final report on the Project, including updated integrated product development plan (IPDP) and financial reports (budget and actuals), with indication of unspent or uncommitted grant funds distributed to PnuVax by the Foundation within 30 days of your receipt of this letter. Templates for final report, IPDP and budget to be updated will be provided to you by email.

- PnuVax should return to the Foundation via a wire, as per the attached instructions, all grant funds that have not been used for, or committed to, the Project. The wire must be received by the Foundation within 30 days of your receipt of this letter.

- In accordance with the Grant Agreement, PnuVax was required to apply all interest earned on grant funds for the purposes of the Project, and this was not done. PnuVax should return to the Foundation via a wire, as per the attached instructions, an amount equal to the interest earned on the grant funds held in the trust account of Mullowney's Law. The wire must be received by the Foundation within 30 days of your receipt of this letter. In addition, please explain how the amount of interest was calculated.

- In addition to the applicable obligations under the Grant Agreement, this is a reminder that, in accordance with its terms, the Global Access Agreement is continuous and survives termination of the Grant Agreement. Accordingly, PnuVax remains obligated to comply in full with the obligations thereunder.

- PnuVax is no longer eligible to receive future grant funding from the Foundation. The Foundation will consider reinstating such eligibility upon receipt of evidence that PnuVax has complied in full with the requirements set forth above.

The Foundation regrets having to terminate the Grant Agreement, and it is our desire to resolve this matter amicably to the extent possible. Accordingly, we will appreciate PnuVax's prompt attention to this letter, and your cooperation in resolving this matter as expeditiously as possible.

Sincerely,

Trevor.

Trevor Mundel, MD, PhD
President, Global Health Program
V +1.206.709.3253
F +1.206.494.7041
E trevor.mundel@gatesfoundation.org

cc: Keith Klugman, Director, Pneumonia
cc: Ruth Atherton, Director, Legal
cc: J. L. Lee Mullowney,
email lee@mullowney.com
Mullowney's Law, Professional Corp.
Fairmont Chateau Laurier
1 Rideau Street, Suite 700
Ottawa, ON K1N-8S7

Attachments
1) Wire instructions
2) Final report template
3) Integrated product development plan
4) Budget template